

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

UNITED STATES OF AMERICA
ex rel. SUSAN HUTCHESON and
PHILIP BROWN,

BRINGING THIS ACTION ON BEHALF
OF THE UNITED STATES OF AMERICA,

Plaintiffs and Relators,

v.

BLACKSTONE MEDICAL, INC., n.k.a
ORTHOFIX SPINAL IMPLANTS

Defendant.

Civil Action No. 1:06-cv-11771-WGY

AMENDED COMPLAINT FOR VIOLATIONS OF THE FALSE CLAIMS ACT

I. INTRODUCTION.

1. Qui Tam Relators Susan Hutcheson and Philip Brown bring this action on their own behalf and on behalf of the United States of America to recover damages and penalties under the False Claims Act, 31 U.S.C. § 3729 *et seq.*, against Defendant Blackstone Medical, Inc., now known as Orthofix Spinal Implants. The violations arise out of Defendant's actions to cause the submission of false claims for payment to Medicare, Medicaid, and other federally-funded government healthcare programs for spinal surgeries involving Defendant's device, implantation, and instrumentation products.

2. This amended complaint details fraudulent schemes employed by Defendant to increase the use of its products in spinal surgeries by systematic payment of kickbacks to physicians throughout the United States in the form of sham consulting

agreements, research grants, entertainment, travel, and other illegal incentives in order to induce those physicians and other health care providers to use their surgical devices, implants, and instrumentation products.

II. JURISDICTION AND VENUE.

3. This action arises under the United States Civil False Claims Act, 31 U.S.C. § 3729 *et seq.*

4. The Court has subject-matter jurisdiction pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1331, and has personal jurisdiction over the Defendant because the Defendant does business and is located in this District.

5. Venue lies under 28 U.S.C. § 1391(b), (c) and 31 U.S.C. § 3732(a) because Defendant Blackstone Medical Inc. operates and transacts business within this district.

6. At the time of filing of the original complaint, the allegations of this complaint were not publicly disclosed in a criminal, civil, or administrative hearing, nor in any congressional, administrative, or General Accounting Office report, hearing, audit, or investigation, nor in the news media.

7. As further discussed in paragraphs 10-16 below, each Relator is an original source of the information upon which this complaint is based, as that phrase is used in the False Claims Act and other laws at issue herein.

8. Relators provided disclosure of the allegations of this complaint to the United States prior to filing. Relators disclosed the allegations of the complaint to the United States Attorneys' Office for the Middle District of Florida in the Summer of 2006,

and disclosed the allegations of the complaint to the United States Attorneys' Office in the District of Massachusetts in October 2006.

III. PARTIES.

9. The real party in interest to the claims set forth herein is the United States of America.

10. Relator Susan Hutcheson is a resident of Florida and a citizen of the United States. Relator Hutcheson was employed as a Regional Manager by Blackstone Medical Inc. from January 2004 until she was terminated in January 2006.

11. Relator Hutcheson has direct and independent knowledge of the allegations in this amended complaint. She personally observed Defendant's practices while in their employ, and was privy to meetings, conversations, and other internal communications. In the regular course of her job duties, she also had access to email and internal documents and data which reflected the conduct discussed herein, including communications and documents circulated among upper management.

12. In the course of her job duties at Blackstone, Relator Hutcheson had many interactions with managers, employees, distributors, sales representatives, physicians, and hospital representatives relating to Defendant's business practices. Her close interactions with such persons support and confirm the allegations herein.

13. Relator Hutcheson has had ongoing interactions with many of these individuals, based on her established relationships with them and her position in the industry. She has worked in sales and marketing positions in the spine industry since

1995. After being terminated by BMI, Relator Hutcheson continued to work in the industry.

14. Relator Philip Brown is a resident of Florida and a citizen of the United States. Relator Brown worked as an independent distributor for BMI in 2004.

15. In the course of his duties as a distributor, Relator Brown had interactions with managers, sales representatives, physicians, and hospital representatives relating to Defendant's business practices, including as part of his efforts to develop a BMI consulting relationship with physicians in his territory. As part of those efforts, he had meetings with BMI representatives and physicians in an attempt to convert business to BMI. His interactions with these individuals supported and confirmed many of all allegations herein.

16. Relator Brown has continuing relationships with other sales representatives. He has worked in sales positions in the spine industry since 1991. After leaving BMI, he distributed surgical products for another manufacturer, but has since left the industry.

17. Defendant Blackstone n/k/a Orthofix Spinal Implants was a privately-held company created in 1996 and headquartered in Springfield, Massachusetts. The company was formed by brothers Bill Lyons, Mike Lyons, and Matt Lyons. BMI designs, develops and markets spinal implant and related biologics products.

18. Defendant Blackstone n/k/a Orthofix Spinal Implants offers and pays illegal incentives to physicians in this jurisdiction, and all over the country, as discussed herein and specifically identified in paragraphs 85.

19. Orthofix International N.V. is a global company founded in Verona, Italy in 1980. Orthofix International is headquartered in Curacao, Netherlands Antilles and has corporate offices in Springfield, Massachusetts and Huntersville, North Carolina. Orthofix's subsidiary, Orthofix Orthopedics, designs, develops, manufactures, markets, and distributes medical equipment used principally by musculoskeletal medical specialists for orthopedic applications. Orthofix Orthopedics North American offices are in McKinney, Texas.

20. Orthofix International completed acquisition of Blackstone in September 2006 for \$333 million.

21. Blackstone continued to operate from its Springfield offices after it was bought by Orthofix. After acquisition, Orthofix identified Blackstone in public filings as one of four business segments: Domestic, Blackstone, Breg, and International. In March 2007, Orthofix announced:

We have designated Blackstone, our newly acquired subsidiary, as a business segment. Blackstone specializes in the design, development and marketing of spinal implant and related biologic products. Blackstone uses distributor sales representatives to sell Spine products domestically and internationally.

Form 10-K, March 16, 2007.

22. In July 2008, Orthofix promoted Brad Mason, the President of the Orthofix Sports Medicine Division, to Group President of Blackstone's North American offices, and then, in August 2008, to President of Blackstone. In November 2008, Orthofix announced that it was restructuring Blackstone, and would be consolidating its operations in Wayne, NJ, and Springfield, MA, into the same McKinney, Texas facility

which housed Orthofix spine stimulation and U.S. orthopedic operations. This consolidation was expected to begin immediately and continue through 2009, with reduced operating expenses to be realized by 2010 (Orthofix Press Release, November 6, 2008). In a 2009 quarterly report, Orthofix describes its business segments as: Domestic, Spinal Implants and Biologics, Breg, International, and Group Activities. The Spinal Implants and Biologics segment “consists of Blackstone, based in Springfield, Massachusetts and its two subsidiaries, Blackstone GmbH and Goldstone GmbH. Spinal Implants and Biologics specializes in the design, development and marketing of spinal implant and related human cellular and tissue based products (“HCT/P products,” often referred to as Biologic products). Spinal Implants and Biologics distributes its products through a network of domestic and international distributors, sales representatives and affiliates.”

23. Blackstone was recently renamed “Orthofix Spinal Implants.” Defendant Blackstone, now known as Orthofix Spinal Implants, shall be referred to herein as Defendant or Blackstone or BMI.

IV. THE STATUTORY AND REGULATORY ENVIRONMENT.

24. BMI illegally induced physicians to perform surgeries using its spinal surgery products through payment of illegal kickbacks. As a result of BMI’s illegal inducements, physicians performed surgeries using BMI products on Medicare and Medicaid patients admitted at healthcare facilities around the country. By so doing, BMI caused hospitals to submit false claims for payment of these surgeries performed in violation of the Anti-Kickback Act.

A. THE ANTI-KICKBACK ACT.

25. Under the Medicare and Medicaid Patient Protection Act, 42 U.S.C. § 320a-7b(b) (the “Anti-kickback Statute”), it is unlawful to knowingly offer or pay any remuneration in cash or in kind in exchange for the referral of any product for which payment is sought from any federally-funded health care program, including Medicare, Medicaid, and TRICARE.

26. The Anti-kickback Statute is designed to, *inter alia*, ensure that patient care will not be improperly influenced by inappropriate compensation from the healthcare industry.

27. Each of the federally-funded health care programs requires every provider who seeks payment from the program to promise and ensure compliance with the provisions of the Anti-kickback Act and other federal laws governing the provision of health care services in the United States.

28. The Anti-kickback Statute prohibits medical device manufacturers and suppliers from compensating, in cash or in kind, a physician when a purpose of the payment is to influence the physician’s use of its product over the product of any competitor.

29. Examples of activities prohibited by the Anti-kickback Statute include payments for sham consulting services, illusory training sessions, bogus research and educational grants, bogus speaking fees, lavish entertainment, travel and lodging expenses, expensive meals and wine, and other gifts and discounts. These activities are especially suspect if the medical device supplier selects the physician based on its

belief that the physician is likely to prescribe the company's products rather than on the physician's professional qualifications or services he or she actually rendered to the company.

30. The Anti-kickback Statute provides certain "safe harbors" to exclude certain conduct from its ambit, as long as the involved parties have strictly complied with all the conditions of the safe harbor. However, parties to an arrangement cannot obtain safe harbor protection by entering into a sham contract that complies with the written agreement requirement of a safe harbor and appears, on paper, to meet all of the other safe harbor requirements, but does not reflect the actual arrangement between the parties.

31. There is a safe harbor for personal service arrangements which requires, among other things, that:

The aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs; and

The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

42 C.F.R. § 1001.952(d) (5), (7).

32. BMI does not meet these requirements, because it offers incentives to providers based on the volume or value of business it expects the provider to generate.

33. BMI does not pay physicians in a manner consistent with fair market value in an arms' length transaction, nor does it engage them for commercially reasonable business purposes. Rather, BMI "engages" physicians based on its own sales needs.

B. REIMBURSEMENT BY GOVERNMENT-FUNDED HEALTH CARE PROGRAMS.

34. The Health Insurance for the Aged and Disabled Program, popularly known as Medicare, was created in 1965 as part of the Social Security Act (SSA). The Secretary of Health and Human Services ("HHS") administers the Medicare Program through the Centers for Medicare and Medicaid Studies ("CMS"), a component of HHS.

35. The Medicare program consists of two parts. Medicare Part A authorizes the payment of federal funds for hospitalization and post-hospitalization care. 42 U.S.C. § 1395c-1395i-2 (1992). Medicare Part B authorizes the payment of federal funds for medical and other health services, including without limitation physician services, supplies and services incident to physician services, laboratory services, outpatient therapy, diagnostic services, and radiology services. 42 U.S.C. § 1395(k),(i), (s).

36. The Medicaid program was also created in 1965 as part of the Social Security Act, which authorized federal grants to states for medical assistance to low-income persons, blind, disabled, or members of families with dependent children or qualified pregnant women or children. The Medicaid program is jointly financed by the federal and state governments. CMS administers Medicaid on the federal level. Within broad federal rules, each state decides eligible groups, types and range of services, payment levels for services, and administrative and operating procedures. The states directly pay providers, with the states obtaining the federal share of the payment from

accounts which draw on the United States Treasury. 42 C.F.R. §§ 430.0-430.30 (1994).

The federal share of each state's Medicaid expenditures varies by state.

37. Various other federally-funded medical coverage programs exist to help discrete populations of enrollees obtain medical care, including the Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS"), TRICARE, and the Veterans Administration, among others.

38. Reimbursement practices under all federally-funded healthcare programs closely align with the rules and regulations governing Medicare reimbursement.

39. Reimbursement for Medicare claims is made by the United States through CMS which contracts with private insurance carriers to administer and pay claims from the Medicare Trust Fund. 42 U.S.C. § 1395u. In this capacity, the carriers act on behalf of CMS. 42 C.F.R. § 421.5(b) (1994).

40. Faced with escalating costs and concerned about inefficiency, Congress fundamentally overhauled the Medicare reimbursement methodology in 1983, establishing the Prospective Payment System ("PPS") to reimburse hospitals for the operating costs of inpatient healthcare services rendered to Medicare beneficiaries. Pub. L. No. 98-21, 97 Stat. 65 (1983) (codified as amended at 42 U.S.C. § 1395ww(d)); 42 C.F.R. Pt. 412 (2001). With certain exceptions, PPS reimburses hospitals for inpatient Medicare services according to a per-patient standardized rate, called the Diagnostic Related Group ("DRG") rate. 42 U.S.C. § 1395ww(d)(3)(A), (D).

41. CMS calculates DRG rates prospectively based on estimates of total Medicare reimbursements for the upcoming fiscal year. 42 U.S.C. § 1395ww(d)(2)(A)-

(C); 42 C.F.R. § 412.62. To calculate reimbursement for individual patients, the Secretary annually adjusts the average rate by the average cost of diagnosing and treating patient with similar conditions as those in the DRGs. 42 U.S.C. § 1395ww(d)(3)-(4), (5); 42 C.F.R. § 412.60. The Secretary also makes additional payments for certain services that are extraordinarily costly, known as "outlier payments," up to a threshold amount. 42 U.S.C. § 1395ww(d)(5)(A)(i)-(iv).

42. Congress had four objectives in creating the PPS:

1. To ensure fair compensation for services rendered and not compromise access to hospital services, particularly for the more seriously ill;
2. To ensure that the process for updating payment rates would account for new medical technology, inflation, and other factors that affect the cost of providing care;
3. To monitor the quality of hospital services for Medicare beneficiaries; and
4. To provide a mechanism through which beneficiaries and hospitals could resolve problems with their treatment.

Medicare Hospital Prospective Payment System: How DRG Rates Are Calculated and Updated, Office of Inspector General, Office of Evaluation and Inspections, White Paper (August 2001), *citing, generally*, H.R. REP. NO. 25, 98th Cong., 1st Sess. 132 (1983), S. REP. NO. 23 98th Cong., 1st Sess. 111 (1983).

43. Hospitals submit claims for interim reimbursements for services delivered to specific Medicare beneficiaries during their hospital stays. 42 C.F.R. §§ 413.1, 413.60, 413.64. Hospitals submit patient-specific claims for interim payments on Form CMS-1450, also called Form UB-92.

44. As a prerequisite to payment, CMS requires hospitals to submit annually a form CMS-2552, commonly known as the Hospital Cost Report. 42 U.S.C. § 1395g(a); 42 C.F.R. § 413.20. The cost report is the provider's final claim for payment from the Medicare program for the services rendered to program beneficiaries for the period it covers. The cost report includes all of the provider's costs, accounts for them under applicable provisions of the Medicare statute and regulations and HCFA program instructions, and results in a claim for a total amount of program reimbursement for the fiscal year.

45. Medicare reimburses physicians for their professional services under Part B of the program, pursuant to a Physician Fee Schedule ("PFS"). 42 C.F.R. § 414.58(a). Physician fees under the PFS are determined according to a standardized coding system assigned to procedures set forth in the Health Care Financing Administration's Common Procedure Coding System (HCPCS).

46. Under the HCPCS, standardized codes, called Current Procedural Terminology ("CPT") codes, are assigned to various procedures. CPT codes are maintained by the American Medical Association, and the CPT code set was adopted by CMS for the reporting of services under Part B of the Medicare program. The CPT code set accurately describes medical, surgical, and diagnostic services and is designed to communicate uniform information about medical services and procedures among physicians, coders, patients, accreditation organizations, and payers for administrative, financial, and analytical purposes.

47. The CPT code assigned to a medical procedure determines the payment amount to the physician under Part B. The payment amount for each service paid under the Physician Fee Schedule (“PFS”) is the product of three factors—(1) a nationally uniform relative value for the service; (2) a geographic adjustment factor for each physician fee schedule area; and (3) a uniform conversion factor for the service.” Final Rule, 68 Federal Register 63190 (November 7, 2003). For each physician service, there are three relative values: for physician work; for practice expense; and for malpractice expense. *Id.* These are referred to as Relative Value Units (“RVU’s”). The work RVU’s are based on national valuations of physician time expended for a particular service, and can be accessed on CMS’s website in published schedules.

48. Thus, the DRG system establishes standardized payments for Part A (inpatient) services, and the CPT system established a standardized payment amount for physician services, based on evaluation of the actual average costs of performing that procedure, by region and type of provider, as reported by providers annually.

49. Physicians submit claims for their professional services to Part B of the program on Form CMS-1500.

1. Reimbursement for Surgeries Using the Medical Devices at Issue

50. Costs associated with spine surgery utilizing medical devices are separately billed by the hospitals and surgeons to payors, including Medicare, Medicaid, and TRICARE.

51. Hospitals submit claims to federal programs for the inpatient costs associated with the surgeries, including the cost of the medical devices, on interim

claims forms called Forms CMS-1450 (formerly UB-92's) and hospital cost report forms (the final claim). Hospital claims identify the DRG associated with the surgery, which CMS uses to determine the payment amount to the hospital, to include payment for the medical devices used during the surgery.¹

52. DRG codes are calculated in a manner intended to fairly compensate the hospital for all the costs associated with the surgery, including the medical device costs. DRG rates are recalculated annually based on, among other things, actual claims data.

53. The surgeon performing the surgical procedure separately bills for his or her professional services on a Form CMS-1500, identifying the surgical procedure by the appropriate CPT code.

54. Each orthopedic surgeon chooses which manufacturer's spine hardware to use in each surgery. However, the devices utilized in a spinal surgery are generally purchased by the hospital from the manufacturer (*see infra* section V.F. discussing procedure for ordering and purchasing of devices).

55. The surgical devices used in spinal surgery include various products that are used to stabilize an injured or degenerating spine. Products used in cervical spinal surgery (neck) include anterior cervical plates and screws, lateral mass screws and rods, laminoplasty plates and screws and bone products, such as bone spacers or cellular bone matrix. Products used in lumbar spinal surgery (lower back) generally consist of pedicle screws and rods, interbody devices such as peek spacers, or

¹ Medical devices are generally encompassed within the DRG reimbursement. A small minority of devices are identified as "pass-through" devices, which are paid separately.

corpectomy devices such as mesh spacers, anterior buttress plates and some bone products such as bone spacers and cellular bone matrix.

2. Compliance with the AKA is a Condition of Payment

56. Compliance with the Anti-kickback Statue is a condition of payment for federally-funded healthcare programs, including Medicare, Medicaid, and TRICARE, meaning that if a provider tells CMS or its agent that it provided services in violation of the Anti-kickback Statute, CMS will not pay the claim.

57. Hospitals and physicians enter into Provider Agreement with CMS in order to establish their eligibility to seek reimbursement from the Medicare Program. As part of that agreement, without which the hospitals and physicians may not seek reimbursement from federal health care programs, the provider must sign the following certification:

I agree to abide by the Medicare laws, regulations and program instructions that apply to [me]. The Medicare laws, regulations, and program instructions are available through the [Medicare] contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the [provider's] compliance with all applicable conditions of participation in Medicare.

Form CMS-855A; Form CMS-855I.

58. When a hospital submits a claim for payment, it does so subject to and under the terms of its certification to the United States that the services for which payment is sought were delivered in accordance with federal law, to include without limitation the Anti-kickback Statue.

59. When a physician submits a claim for payment, he or she does so subject to and under the terms of its certification to the United States that the services for which payment is sought were delivered in accordance with federal law, to include without limitation the Anti-kickback Statute.

60. Every Hospital Cost Report also contains a Certification which must be signed by the chief administrator of the provider or a responsible designee of the administrator.

61. The CMS Form 2552 Hospital Cost Report certification page includes the following statement:

Misrepresentation or falsification of any information contained in this cost report may be punishable by criminal, civil and administrative action, fine and/or imprisonment under federal law. Furthermore, if services identified in this report provided or procured through the payment directly or indirectly of a kickback or where otherwise illegal, criminal, civil and administrative action, fines and/or imprisonment may result.

62. The cost-report certifier is also required to certify that:

To the best of my knowledge and belief, it [the Hospital Cost Report] is a true, correct and complete statement prepared from the books and records of the provider in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding the provisions of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations.

63. Thus, by signing CMS Form 2552, a hospital provider is required to and does certify that its cost report was (1) truthful, i.e., that the cost information contained in the report is true and accurate; (2) correct, i.e., that it is entitled to reimbursement for the reported costs in accordance with applicable instructions; (3) complete, i.e., that the cost

report is based upon all information known to the provider; (4) did not include any services that resulted from an illegal kickback; and (5) the services provided in the cost report were billed in compliance with all provisions of the Stark laws.

64. As a result of the systematic payment of kickbacks to physicians made with the intent and effect of inducing them to use its spinal surgery products, BMI caused hospitals to submit claims in violation of conditions of payment and claims with false certifications to the United States. Claims submitted as a result of illegally-induced surgeries were false claims.

V. FACTUAL ALLEGATIONS

65. BMI used a business model which depended on paying surgeon, in cash and in kind, to use BMI products in surgeries on their patients.

66. BMI's senior management and owners knew that Medicare, Medicaid and other federal program beneficiaries represent a significant percentage of spine-surgery patients.

67. As explained in detail below, BMI offered and paid remuneration far in excess of fair market value. This remuneration took such forms as, *inter alia*, monthly payments under sham consulting agreements; paid development projects; research grants; royalties; exorbitant and sometimes illicit entertainment expenses; high-end travel and accommodations; speaking engagements and seminars, and other illegal incentives.

68. BMI's business model was centered around offering and paying illegal incentives to increase the use of its products in spinal surgeries performed nationwide.

69. BMI executed its business model through its sales team, which was responsible for targeting high volume surgeons and offering incentives to convert their business to BMI.

70. The BMI sales team was directly supervised by BMI founder, co-owner, and President Matt Lyons. BMI's Vice President of Sales, Paul Sendro, reported to Mr. Lyons, and led a team composed of two divisional managers (Eastern and Western) and six to seven regional managers (Northeast, Midwest, Southeast, Gulf Coast, Southwest, Mountain, Pacific and Northwest).

71. Regional managers supervised independent distributors, who are responsible for sales in particular territories within their region. The independent distributors and sales representatives they employed had direct contacts with the surgeons and hospitals. Distributors received commissions based on a percentage of sales in their territory.

A. BMI'S MEDICAL ADVISORY BOARD ("MAB") CONSULTANT SCHEME

72. One of the primary ways in which BMI executed its business model was to pay surgeons to be members of its Medical Advisory Board ("MAB") under consulting agreements which purported to engage them to develop and evaluate BMI products. These surgeons were called "MAB's."

73. The MAB consulting agreements were shams. MAB contractors were paid amounts far above the fair market value of whatever services they might have provided, and for commercially unreasonable purposes, in order to induce them to increase the number of surgeries performed using BMI products.

74. Under their BMI contracts, MAB contractors were paid a monthly stipend, ranging in numbers from \$1,666 per month to \$8,000 per month.

75. Regional managers received monthly reports indicating the consulting fees paid to MABs. "Regional Sales Performance Scorecards," also generally referred to as "Monthly Report Cards," were distributed to regional managers every month. In addition to the contracts themselves, these reports reflected the monthly fees and commissions applicable to a particular region.

76. BMI openly viewed MAB contractors as a guarantee of increased sales volume.

77. This nexus was so basic to BMI's business model that it reduced the commissions of its sales distributors by half of the consulting fees paid to MAB's within the distribution territory. BMI called the distributor's contribution to the MAB fees a "territory development fee."

78. The BMI sales team's activities were in large part consumed with identifying and targeting high volume surgeons as candidates for MAB status and other arrangements and incentives.

79. Physicians were chosen as MAB's on the basis of the volume of business BMI projected that the physician would generate. BMI distributors were instructed to fill out a "Surgeon Visit Questionnaires" prior to having potential MAB doctors meeting with BMI management. These forms set out the surgeon's "Annual Sales with Blackstone Medical."

80. Surgeons targeted for a MAB contract (or in BMI parlance, “teed-up” for a contract) were invited to BMI offices for a “VIP visit”. A BMI handout dated June 2004 entitled “MAB Initiation and Management Process” identifies a process whereby, among other things:

- The VP of Sales (Bob Hastings) identifies a “need;”
- The “need” is approved by “Blackstone’s Executive Team;”
- Professional Relations qualifies a candidate;
- The candidate is interviewed by “Department Heads;”
- A contract is presented, then signed by surgeon and the President.

81. BMI did not follow this process as spelled out in the handout, but it accurately reports that senior management knew of and approved every MAB contract.

82. Robert Hastings, Vice President of Technology Development and Professional Relations, was in charge of the development and oversight of the MAB program. President Matt Lyons was also significantly involved in that process, including in the signing of every MAB agreement.

83. By way of example, on August 19, 2004, Robert Hastings sent an email titled “MAB Protocols” to BMI Management including Relator Hutcheson, which reveals his and Matt Lyons’ involvement in the individual selection of MABs. Mr. Hastings instructs:

Before I speak with ANY surgeon regarding that individual being an MAB potential member, there must be the Pre-Approval document signed off and in Monique’s² possession. If that document is not in place I will not speak to any surgeon regarding the possibility of him being an MAB member. No Exceptions! This will eliminate any and all confusion about when and what the next action item will be. Matt Lyons or myself are the only individuals that can authorize the date of when an agreement is going to be sent out.

² Monique Distasi was Mr. Hasting’s assistant in this time frame.

The next day, Mr. Hastings explained that only senior BMI management controlled the ultimate selection of MAB contractors: “The Pre-Approval form is only for Executive Management.” (August 19, 2004 email from Robert Hasting to BMI Management, titled “RE: MAB Protocols”).

84. BMI engaged an enormous number of surgeons through paid consulting agreements. There were at least 91 doctors who have had consulting agreements with BMI since its inception in 1996. Doctors who were offered/or paid remuneration by BMI pursuant to consulting or other paid arrangements include, without limitation, those identified in the following chart, along with their location, affiliated hospital, and billing number, if known:

First Name	Last Name	Location	Hospital	UPIN
William E.	Adams	Columbus, GA		
David Fernando	Antezana	Portland, OR	Providence St. Vincent Medical Center Providence Portland Medical Center Legacy Emmanuel Hospital Legacy Good Samaritan Hospital	H12692

First Name	Last Name	Location	Hospital	UPIN
			Johns Hopkins University Hospital	
Lawrence "Brett"	Babat	Nashville, TN	Skyline Medical Center Nashville Premier Orthopaedics Surgery Center Nashville Hendersonville Hospital Tennessee Christian Medical Center Nashville Memorial Hospital Williamson Medical Center Centennial Medical Center Saint Eugene Medical Center Baptist Hospital	H15986
Hugo Ermel	Benalcazar	Baltimore, MD	Good Samaritan Hospital of MD, INC. Greater Baltimore Medical Center	H25406

First Name	Last Name	Location	Hospital	UPIN
			Northwest Hospital Center (LifeBridge Health) Saint Joseph Medical Center Sinai Hospital of Baltimore (LifeBridge Health) Upper Chesapeake Health System Center/Harford Memorial Hospital Sinai Hospital and Spine Center	
Scott	Blumenthal	Plano , TX	Presbyterian Hospital Of Plano Presbyterian Center For Diagnosis & Surgery Las Colinas Medical Center	C13561
Kevin	Booth	Pleasanton, CA	ValleyCare Medical Center San Ramon Regional Medical Center Washington Hospital	G66858
Renato Victor	Bosita, Jr.	Plano , TX	Plano Presbyterian Hospital Plano Presb Center	H55259

First Name	Last Name	Location	Hospital	UPIN
			Diagnostics & Surgery Baylor Surgicare of North Garland	
William Daniel	Bradley	Denton, TX	Denton Regional Medical Center Presbyterian Frisco Medical Center North Texas Hospital Baylor Surgicare PPCDS	H25888
Timothy A.	Burd	Omaha, NE	Alegent Health Systems Methodist Health System Nebraska Othopaedic Hospital	H63177
Daniel Alexander	Capen	Oxnard, CA	Pacific Hospital of Long Beach Little Company of Mary Hospital Sherman Oaks Hospital Health Center Los Robles Medical Center Mission Community Hospital	G32316
Patrick D.S.	Chan	Searcy, Arkansas	Suspended	H21779

First Name	Last Name	Location	Hospital	UPIN
Mokbel	Chedid	Detroit, MI	Genesys Regional Medical Center Henry Ford Hospital	G08960
Ronald Clayton	Childs	Fairfax, Virginia	Inova Fair Oaks Hospital Inova Fairfax Hospital Reston Hospital Center	F29701
Joseph D.	Ciacci	Baltimore, MD	Sinai Hospital of Baltimore Inc. Levindal Hebrew Ger. Center & Hospital Saint Agnes Hospital The Johns Hopkins Hospital	G81439
Michael A.	Cowan	Rock Hill, SC	Piedmont Medical Center Carolinas Medical Center Presbyterian Hospital	H01810
Randy F.	Davis	Glen Burine, MD	Baltimore Washington Medical Center f/n/a North Arundel Hospital Johns Hopkins Bayview Medical Center Bayview Nursing Johns Hopkins Geriatrics Center	D70352

First Name	Last Name	Location	Hospital	UPIN
			Johns Hopkins Hospital	
M. David	Dennis	San Antonio, TX	South Texas Spine & Surgical Hospital Del Sol Medical Center	C15182
Curtis	Dickman	Phoenix, AZ	St. Joseph's Hospital & Medical Center Barrow Neurological Institute	F28175
Janet G.	Dunlap	Oceanside, CA	Tri-City Medical Center Scripps Mercy Hospital	F05341
Chris Reading	Edwards	Marietta, GA Atlanta, GA	Atlanta Medical Center Northside Hospital Crawford Long Hospital Piedmont Hospital DeKalb Medical Center Southwest Hospital Orlando Regional Medicine Center, Internal Medicine	
Stephen Ivon	Esses	Houston, TX	The Methodist Hospital VA Hospital	F07242

First Name	Last Name	Location	Hospital	UPIN
			Twelve Oaks Medical Center St. Lukes Episcopal Hospital Methodist Hospital Texas Children's Hospital	
Kenneth Dewayne	Eubanks	Jonesboro, AR	Regional Medical Center of Northeast Arkansas Northeast Arkansas Medical Center Saint Bernard's Medical Center The Surgical Hospital of Jonesboro	G55071
Brent A.	Felix	Salt Lake City, UT	Logan Regional Hospital Salt Lake Regional Medical Center	G33954
Brian C.	Fitzpatrick	Scottsdale, AZ	Saint Joseph's Hospital Medical Center Scottsdale Healthcare-Osborn	F66653
Jason E.	Garber	Las Vegas, NV	Sunrise Hospital & Medical Center	H25467
Jatinder	Gill	Boston, MA	Massachusetts General Hospital	H36308

First Name	Last Name	Location	Hospital	UPIN
			Winchester Hospital	
William Ward	Goodman, III	Springfield, MO	Saint John's Regional Medical Center	G22539
Joseph Martin	Grant	Pleasanton, CA	Valley Care Medical Center San Ramon Valley Regional Medical Center Washington Hospital	E78138
Jaswinder	Grover	Las Vegas, NV	MountainView Hospital Valley Hospital Sunrise Hospital St. Rose Siena Hospital	
Mark Richard	Grubb	Canton, OH	Mercy Hospital of Tiffin Park West Surgical Center Mercy Medical Center	
Jerome Christopher	Hall	San Diego, CA	Scripps Mercy Hospital Sharp Memorial Hospital	
Todd Joseph	Harbach	Springfield, MO	Saint John's Regional Medical Center	F58421
Michael G.	Hill	Leesburg, FL Atlantis, FL 33462	Leesburg Regional Med Center North JFK Medical Center	G10232

First Name	Last Name	Location	Hospital	UPIN
			Palms West Hospital	
Gregory A.	Hoffman	Fort Wayne, IN	Kosciusko Community Hospital Parkview Hospital	E03624
Kade T.	Huntsman	Salt Lake City, UT	Saint Mark's Hospital	G74878
Kamal Naguib	Ibrahim	Oakbrook Terrace, IL Naperville, IL 60563	Advocate Good Samaritan Hospital Adventist Hinsdale Hospital	C45286
Fred Richard	Jordan	North Little Rock, AR	Saint Vincent Medical Center Arkansas Surgical Hospital Saint Vincent Medical Center	
Mark Bradley	Kabins	Las Vegas, NV	Valley Hospital Medical Center	E94199
Paul M.	Keller	Melbourne, FL	Holmes Regional Medical Center	F87718
Eubulus John	Kerr, III	Shreveport, LA Indianapolis, IN	Doctors Hospital Of Shreveport	H64433
Akhil Jay	Khanna	Baltimore, MD	Good Samaritan Hospital	H97016
Kee D.	Kim	Sacramento, CA Saratoga, CA	University Of CA Davis Medical Center	A52119

First Name	Last Name	Location	Hospital	UPIN
Jeffrey Alan	Kozak	Houston, TX	Texas Orthopedic Hospital	B24100
Phillip Robert	Kravetz	Little Rock, AR Irving, TX	Saint Vincent Doctors Hospital Baptist Health Medical Center Las Colinas Medical Center	H32037
Todd Hopkins	Lanman	Beverly Hills, CA	UCLA Medical Center	E29483
Mesfin	Lemma	Baltimore, MD	Good Samaritan Hospital The Johns Hopkins Hospital	H63603
Marc A.	Letellier	Mesa Arizona	Chandler Regional Hospital	B54552
Adam Isaac	Lewis	Jackson, MS	Saint Dominic Jackson Memorial	G28405
Raymon J.	Linovitz	Encintas, CA	Scripps Memorial Hospital	G16599
Mark	Lorenz	Hinsdale, IL	Advocate Good Samaritan Hosp	D15278
Michael Doyle	Mason	Brookline, MA	Boston Medical Center New England Baptist Hospital Newton-Wellesley Hospital	E65190
Bill	Mastrodimos	San Diego, CA	San Diego Kaiser Permanente Hospital	G76386
Nicholas Robert	Mataragas	Lombard, IL	Edward Hines Jr VA Hospital Central DuPage Hospital	H63416

First Name	Last Name	Location	Hospital	UPIN
Anis Onsy	Mekhail	Chicago, IL Palos Heights, IL	Palos Community Hospital Christ Advocate Medical Center University of Illinois at Chicago Medical Center	H65851
Alan Wayne	McGee	Fort Wayne, IN	Parkview Hospital Lutheran Hospital of Indiana	E34714
Russell William	Nelson	Thousand Oaks, CA	Los Robles Regional Medical Center St. John's Regional Medical Center Thousand Oaks Surgical Hospital	G38011
James	O'Neill	Nashville, TN	Vanderbilt Centennial Medical Center Vanderbilt Stalworth Rehab	C31102
Richard	Ozuna	Peabody, MA Lynnfield, MA	Emerson Hospital Mount Auburn Hospital New England Baptist Hospital Northeast Hospital Corporation Beverly Hospital Brigham &	F71508

First Name	Last Name	Location	Hospital	UPIN
			Women's Hospital Massachusetts General Hospital Atlanticare Medical Center	
Helson	Pacheco-Serrant	El Paso, TX	Sierra Medical Center Del Sol Medical Center Sierra Providence Rehabilitation Hospital: Providence Memorial Las Palmas Medical Center El Paso Specialty Hospital	C20116
P Ronjon	Paul	Naperville, IL Glen Ellyn, IL Lombard, IL	Central DuPage Hospital Edward Hines Jr VA Hospital	H95930
Frank	Pedlow	Newton, MA	Spaulding Rehabilitation Hospital	F82731
Timothy A.	Peppers	Encinitas, CA	Scripps Memorial Encinitas Scripps Memorial La Jolla	G77254

First Name	Last Name	Location	Hospital	UPIN
Cyril Anthony	Raben	Fayetteville, AR	Washington Regional Medical Center St. Mary's-Rogers Memorial Hospital Northwest Medical Center	E30614
Michael Logan	Ramsey	Odessa, TX	Alliance Hospital Medical Center Hospital Midland Memorial Hospital	G19811
James	Rappaport	Reno, NV	St. Mary's Regional Medical Center Washoe Medical Center Northern Nevada Medical Center Churchill Community Hospital Renown Regional Medical Center	A50457
Michael	Reed	Panama City, FL	Gulf Coast Medical Center HealthSouth Rehabilitation Hospital Northwest Florida Surgery Center	E91535
Howard Reed	Reichman	Provo, UT	Utah Valley Regional Medical Center Timpanogos	F31505

First Name	Last Name	Location	Hospital	UPIN
			Regional Hospital	
Cornelius Michael	Reing	Annandale, VA	Inova Fair Oaks Hospital Inova Fairfax Hospital	B94488
Reynold	Rimoldi	Las Vegas, NV	Sunrise Hospital & Medical Center	E90497
Robert	Rovner	Oakland, CA San Ramon, CA	San Ramon Regional Medical Center John Muir Medical Center	A49182
Marcus Paul	Schmitz	Pensacola, FL	West Florida Regional Medical Center Sacred Heart Hospital	C78509
Gary A.	Schneiderman	Sacramento, CA	Sutter General Hospital Sutter Memorial Hospital Sutter Medical Center	A47285
James	Schwender	Minneapolis, MN	Methodist Hospital Minneapolis	G82634
Navinder	Sethi	Olney, MD	Montgomery General Hospital Howard County General Hospital	H16318
Edward A.	Shadeed	Oklahoma City, OK	Baptist Hospital Mercy Hospital	

First Name	Last Name	Location	Hospital	UPIN
Alexis Paul	Shelokov	Plano, TX	Baylor Regional Medical Center at Plano Childrens' of Dallas Presbyterian Hospital of Dallas Medical Center of Plano Medical City Dallas	C21715
Jeremy	Shore	Peabody, MA	Beverly Hospital New England Baptist Hospital Salem Hospital Winchester Hospital	H87813
Susan	Stephens	Cleveland Heights, OH	South Pointe Hospital Hillcrest Hospital Huron Hospital East	F28178
Gil	Tepper	Sherman Oaks, CA	Sherman Oaks Hospital Health Center Santa Monica/UCLA Encino-Tarzana Regional Medical Center Cantinela Hospital	G68053
Harvey G.	Thomas	Mesa, AZ	Banner Desert Medical Center	G19594

First Name	Last Name	Location	Hospital	UPIN
Robert G.	Watkins, Jr.	Los Angeles, CA	Saint Vincent Medical Center Centinela Freeman Marina Campus	A71307
Robert G.	Watkins, Sr.	Los Angeles, CA	Saint Vincent Medical Center Centinela Freeman Marina Campus	H69453
William Charles	Watters, III	Houston, TX	St. Luke S Episcopal Hospital MedCenter Ambulatory Surgery Center	C23225
Simcha J.	Weller	Boston, MA	Tufts-New England Medical Center Beth Israel Deaconess Medical Center	
L. Erik	Westerlund	Encinitas, CA	Scripps Memorial Hospital	
Jon	White	Irvine, CA	Irvine Regional Hospital and Medical Center	E08478
Lytton	Williams	Los Angeles, CA Long Beach, CA	Saint Vincent Medical Center Pacific Hospital of Long Beach	A48112

First Name	Last Name	Location	Hospital	UPIN
John Isaac	Williams	Fort Wayne, IN		G02121
David	Wimberley	Houston, TX	Texas Orthopedic Hospital Massachusetts General Hospital Brigham and Women's Hospital	H62655
Douglas Sung	Won	Irving, TX	Baylor Medical Center at Irving	I10492
Steven	Yocom	Camden, NJ	Allegheny General Hospital Cooper University Hospital	H11847
Michael Richard	Zindrick	Hinsdale, IL	Advocate Good Samaritan Hospital La Grange Memorial Hospital Hinsdale Hospital	C46245

85. Because BMI paid these doctors with the purpose of inducing the use of products and surgeries claims submitted to Medicare Part A, Medicare Part B, or other federal payors with these provider names and numbers are false claims.

B. BMI'S CORPORATE POLICY

1. The Purpose of the MAB Consulting Agreements Was to Induce the Referral of Healthcare Business Paid in Whole or Part by Federal Payors.

86. BMI's corporate policy and basic business model was to illegally incentivize providers through cash or in kind remuneration in order to secure business.

87. BMI managers and sales representatives knew that the corporate policy and practice of the company was that it paid physicians to use its products, and that BMI could not reach the sales figures demanded by its owners without doing so.

88. Internal communications and reports reflect this policy and practice. For example, in a November 23, 2005 email, BMI Vice President of Sales, Paul Sendro, directed BMI managers to come up with a plan “for hitting the sales number given to your region for 2006 This plan should include the number of MAB’s, number of new product sets, etc. . . . needed to achieve the goal.” The plan was to be presented to BMI’s owners.

89. At the November 10, 2005 Business Review meeting, which included all sales management members, Regional Sales Manager Andrew Janiak sent Relator Hutcheson an “action item” to meet the goals spelled out by Mr. Lyons: “1) Add 3 MAB’s from list provided to Fred and you ...”

90. Top BMI managers considered the addition of MABs to be one of the one principal ways to increase sales of BMI product. For example, on October 9, 2005, Relator Hutcheson responded to a request for information and sent an email titled “Southeast Region ... what is needed for success” to Vice President of Sales Paul Sendro comparing the number of MABs in her region and her sales figures to regions with higher MAB’s, and consequently higher sales figures. Relator Hutcheson wrote,

I have spent some time looking at some things, and here is a synopsis of what the SE region needs to catch up with the other regions. I notice we have so many fewer sets and so many fewer MABs in the region, and as we all know, both are critical and directly proportional to moving Blackstone products.

This was consistent with many other communications at BMI.

91. In a November 2, 2005 email from Fred Munden (General Manager of the Eastern Division) to Vice President Robert Hastings titled "Hot MABs," Mr. Munden identified Drs. Jeremy Shore and Michael Reed, stated the annual sales they were expected to produce and stated that "These [MAB contracts] need to go out for delivery this week as they have been in the works now for quite some time."

92. Mr. Hasting sent out this urgent response to Mr. Munden and several other BMI employees:

I am moving on these surgeons right now! I need your help in completing paperwork. Our Company needs us to move FAST right now and I want to get these agreements in front of Matt Lyons and OUT tomorrow! Fred, Eric, Their Team and My Team will ALL help in completing hours each month without the HASSLE and HEADACHE, but WE need to move RIGHT NOW! BMI is in need of a LIFT and REVERSE in TREND and WE are ALL in this together to DRIVE SALES!

93. Regional Managers regularly sought to increase sales by adding MABs within their regions. Materials prepared by Pacific Region Manager Victor Harmon for a November 10, 2005 Business Review meeting included a slide titled "Opportunities to Grow Current Business/User Base," which is noted "Addition of White and Lavi to MAB team. Could have 100k impact monthly." Upon information and belief, Dr. Jon White and Dr. Simone Lavi became MAB contractors in late 2005.

94. Relator Hutcheson also prepared materials for the Southeast Region for that same meeting based on her understanding of the expectations of BMI, including:

- A slide titled, "Opportunities to Grow Current Business", stating "Michael Reed of Panama City extended a Contract Nov 4th.";

- A slide titled “New Business Targets”, stating “Dr. Brett Babbat from Nashville is scheduled for VIP visit Nov 18th.”;
- A slide titled “Nov & Dec 2005 Goals”, stating “Increase number of MAB surgeons in order to increase business.”

95. Distributer Chris Burdett, who ran Marlin Medical and Associates, Inc., included in his business plan to BMI the addition of new MAB doctors as the main way to increase sales. Marlin’s “2006 Business Plan – Blackstone Medical” states:

My intentions for 2005 are to utilize key MAB surgeons to grow specific geographic areas where Blackstone has no business. This cannot be accomplished without Marlin Medical hiring a competitive Sales Manager (1st Qtr) to help identify MAB prospects ... In order to obtain the 2006 sales goal a minimum of three MAB surgeons are needed.

96. BMI Managers and distributors closely tracked the volume of purchases and ranked all doctors by their sales.

97. BMI regularly compared sales made at the direction of doctors who were MAB contractors against sales made at the direction of non-MAB doctors because sales made by MAB contractors constituted a substantial portion of BMI’s overall sales.

98. By way of example, a chart titled “Consultant Business vs. Total Business Region” for the Southeast region in 2005, breaks down BMI’s total business for each month into the following categories:

- TTL BUS. [Total Business]
- TTL CONS BUS. [Total Consultant Business]
- OTHER BUS [Other Business]
- % Consultant Business
- % NON-MAB Business

The “Consultant Business”, (i.e. MAB contractor business) ranged from 40-60% of BMI’s total sales for each month.

99. Presentation materials prepared by Relator Hutcheson in the course of her job duties titled “An Overview of the SOUTHEAST Region” for 2005 included a section which compares MAB contractor sales (\$1,227,901) to the overall year-to-date sales (\$1,671,612) for Marlin Medical, a company run by distributor Chris Burdett. These figures show that Burdett’s sales on account of MAB contractors constituted 73% of all of his sales for that time period. This is particularly telling, since Mr. Burdett’s base of business was two MAB doctors, and another doctor receiving grants and other incentives.

100. A 2004 chart for Bailey Management Group, another distributor in the Southeast region (eventually the Gulfcoast Region), titled “Total Sales v. Consultant Sales” shows that 73% (\$1,938,490 of \$2,684,504) of its total sales for that year were generated by MAB contractors.

101. Regional Sales Managers were regularly instructed to provide lost revenue reports to BMI senior management. A November 2, 2005 email from Western Divisional Manager Eric Hansen stated that he wanted a report from each regional manager that tracked “Lost revenue from not signing MAB surgeons or inability to provide research/education projects,” as well.

as “Lost revenue due to late MAB payment or nondelivery of contracts.” Mr. Hansen explained to the managers that the report “should be broken down by surgeon or facility the show the dollar figure in lost revenue. **Example** Surgeon A=\$50,000 in lost revenue.”

102. BMI Senior Management believed and expressed the view that lost business was proportional to its failure to provide sufficient paid incentives.

103. BMI Sales Manager for the Northeast Region Andrew Janiak, prepared a “Lost Revenue Report” slide in preparation of a Business Review Meeting held in November of 2005, stating that BMI had lost “100k/month” from its inability to contract Dr. Frank Pedlow as an MAB. This slide also reported losses from its failure to contract numerous other doctors or provide them with research grants, with losses ranging from \$50,000 to \$100,000 per month for each doctor.

104. By way of another example, Dr. Brett Babat is a surgeon at Premier Orthopedics, in Nashville, Tennessee. In 2005, BMI President Matt Lyons spoke with Dr. Babat about an MAB contract and agreed to send him a contract by Thanksgiving. When Dr. Babat did not receive the contract in a timely manner, he switched to using a competitor’s product. An email in December of 2005 to Paul Sendro states:

As you know, Dr. Babbat [sic] was in the NJ office and talked to Matt. Matt told him he would have a contract the week of Thanksgiving[sic], he has been waiting... giving us cases. Now since he does not have a contract, he is now questioning whether he will get the contract and has flipped cases back to [BMI competitor] Depuy.

105. The relationship between the consulting fee and other paid incentives and the development of business is explicitly illustrated by the “territory development fee” charged against the commissions of distributors with MAB’s in their territories. The territory development fees were a method to charge distributors for portions of consulting fees, because such fees secured business in their respective territories.

106. For example, in a February 17, 2005, sales representative Chuck Bolles,

complained to his employer Chris Burdett (owner of Marlin Medical) about a deduction from his commission that is used to royalties on the ICON product to Dr. Paul Keller:

Chris, I am responding to the \$1,125.00 deduction from my Blackstone Commission. What the hell is going on!! Dr. Paul Keller requires a great deal of attention to detail for him to remain loyal to our products as service. As a design surgeon Blackstone Corporate, not the local rep, should FINANCE the Dr.'s royalty agreement. This stinks. There are plenty of spinal companies out there that would like access to Dr. Keller. Need I remind Corporate that Dr. Keller was client long before Blackstone came along. I'm not happy about this deduction and I am sure Dr. Keller is unaware of this deduction. He would not stand for me offsetting the cost of the Icon royalty. Please address this situation with Blackstone Corporate.

107. On January 25, 2005, BMI President Matt Lyon's secretary emailed him regarding whether part of the \$5,000 retainer paid to Dr. Keller should be deducted from BMI's payment to distributor Marlin Medical as a territory development fee. In a responding email, Lyons confirms the deduction.

108. BMI's senior management unquestioningly viewed the payment of incentives to physicians as directly connected to the receipt of their business. For example, BMI tracked its contacts and sales volume with surgeons in weekly reports called the "Monday Reports." The Monday Reports contain the notes of BMI's sales force, including Regional Sales Managers and distributors, categorized as "status updates", "new business", and "lost business."

109. The Monday Reports were circulated among senior management, including the Lyons brothers.

110. The Monday Reports are replete with entries that clearly reflect BMI's corporate policy of targeting high volume surgeons, and offering them paid MAB

arrangements and other incentives in return for the commitment by the doctor to increase his or her utilization of BMI products for surgeries (referred to as “cases”). These reports also reflect that MAB doctors were subject to constant pressure from BMI management to increase their utilization of BMI products, and were routinely reprimanded and sometimes terminated when they did not use enough of BMI products. The reports reflect the direct relationship between a doctor’s commitment to perform surgeries using BMI product and the paid relationship with BMI.

111. The following are specific examples from the Monday Reports which plainly reflect BMI’s corporate policy.

112. **Dr. David Antezana & Todd Keuther.** Drs. David Antezana and Todd Keuther are surgeons at Micro Neurosurgical Consultants PC in Portland, Oregon, and became BMI MAB contractors starting in or before 2005. The Monday Report entries regarding these surgeons clearly show that BMI expected MAB’s to use a certain amount of BMI product in return for the remuneration provided through the consulting agreement.

6/26/05	Status Update: “Kuether and Wright have continued to ‘step up’ cases hence bookings continue to show increases in the NW.”
7/17/05	Status Update: “Pushing Kuether/Antezana/O’Neil for additional cases.”
7/24/05	Status Update: “Mtg w/Kuether & Antezana (7/19) to discuss increasing cases and protocol guidelines.”
8/7/05	Lost Business: “Kuether & Antezana haven’t done a case in over 30 days. Working on setting up appointment w/office & Eric Hansen.”
8/7/05	Status Update: “Antezana & Kuether are not active. <i>This remains a problem as this MAB group isn’t fulfilling agreement.</i> ”

Emphasis supplied.

113. **Dr. Brett Babat.** Dr. Brett Babat is a surgeon at Premier Orthopedics, in Nashville Tennessee. He became a BMI MAB contractor in late 2005. Monday Report entries regarding Dr. Babat reflect BMI's policy of "courting" high volume doctors by bringing them to BMI headquarters (referred to as the "home office") to negotiate their consulting agreement with top BMI officials. Dr. Babat refused to use BMI products in surgeries while he was waiting for BMI to get him the consulting agreement, evidencing his awareness that the consulting agreement was a vehicle through which BMI would pay him to use its product. The entries are:

11/20/05	New Business: "Dr. Babbat did 3 degree & Hallmark last Friday, liked Hallmark."
11/20/05	Status Update: "Dr. Babbat will visit the home office with John and I on Friday Nov 18."
12/4/05	New Business: "1 ICON (Babat) Nashville"
12/18/05	Lost Business: "Dr. Babat has no cases on for this week because he is waiting for initial contract to show "good faith" of working together. Have missed a number of lumbar fusions."
12/25/05	Status Update: "Dr. Babat received his contract and has attorney reviewing it."
1/1/06	Status Update: "Babat moving along and wants to get started working w engineers."

114. **Dr. Kalman Blumberg.** Dr. Kalman Blumberg is a surgeon with South Florida Spine Clinic in Ft. Lauderdale, Florida, and a doctor that Relator Hutcheson suggested to her supervisors might be a good MAB contractor. The Monday Report reveals that BMI's use of consulting agreements as a means to increase sales was

known throughout the company. In this entry, Relator Hutcheson relates to her managers that her highest selling distributor, Chris Burdett, believed that adding three additional MAB's to the region was crucial to increasing sales in the Southeast Region:

10/9/2005 Status Update: "Chris feels that BMI corporate responsible for Blumberg not continuing using Icon. Feels that quota should be reduced, but will not give up territory where he has no representation ant [sic] that he must have 3 more additional MABs in order to increase business."

115. **Dr. Daniel Bradley.** Dr. Daniel Bradley is a surgeon at the Texas Back Institute in Plano, Texas, and an MAB contractor beginning no later than 2004 or 2005. Demonstrating the connection between MAB status and BMI's expectation that their consultants use high volumes of BMI product, the entries emphasized the corporate mindset that Dr. Bradley should not be able to keep his MAB status since he was not using the expected volume of BMI products.

8/7/05 Lost Business: "Dr. Bradley lost! Why is he still a MAB?!?!"

8/7/05 Status Update: "Poor month of July. Dr. Bosita, Bradley had bad months. Why is BMI not on this contract??? Something must be done ASAP!"

116. **Dr. Timothy Burd:** Dr. Timothy Burd is a surgeon at Nebraska Spin Center, LLP in Omaha, Nebraska, and was a BMI MAB contractor beginning no later than December 2005. The Monday Report entries reveal that BMI targeted Dr. Burd due to his position as a high volume surgeon and was courting him as a potential MAB, including flying him out to BMI on a VIP trip to speak personally with Matt Lyons. The entries reflect the quid pro quo between a consulting agreement and his commitment to use BMI product.

6/19/05: Status Update: "In conversation with Dr Burd over the weekend; look for him to step up the business"

6/24/05 Status Update: "We need to talk to Dr. Burd"

7/31/05 Status Update: "Scheduling a VIP trip for Dr Burd to meet with Matt L"

8/7/05 Status Update: "Dr Burd will be coming in to Wayne for a VIP trip to meet Matt L"

8/21/05 New Business: "Dr Burd is going to try the ICON"

9/18/05 Status Update: "Dr Burd is coming to BSM for a VIP Trip. He is totally committed to BSM and really likes his regional manger."

10/02/05 Status Update: "Dr Burd was very impressed with BSM VIP"

10/16/05 Status update: "Dr Burd was very impressed with BSM VIP trip. He will be fully on board and give us lots of support. He wants to try the Unity 51 and Hallmark when it is available."

10/23/05 Status update: "Dr. Burd has not received the paper work he was promised several weeks ago; we need to follow through with our promises or we will lose him to NUVASIVE. I have worked too hard with him to lose his business."

11/13/05 Status Update: "Dr Burd Nebraska has 7 instrumented fusions on the books W/ BSM we will also get his bone business this month 2nd or 3rd week. He is meeting with Julia in Las Vegas this month to discuss Trinity His group is the largest in all of NE 6 spine surgeons are in his group."

11/20/05 New Business: "Dr Burd has agreed to use BSM bone and had a successful week Unity case this past Friday."

11/ 27/05 New Business: "Dr Burd has scheduled a 1st Hailmak [sic] case this week. ***He has agreed to use our lumbar bone and has not received his agreement yet. This is a big concern for me due to his agreeing to support BSM almost 100%.***"

12/11/05 New Business: "Dr Burd has scheduled his 1st Lumbar bone case this Friday along with ASCENT ... Dr Burd is very excited he is finally on board."

12/11/05 Status update: ***"Dr Burd is ready to help in any way with BSM"***

Emphasis supplied.

117. **Dr. William Choi.** Dr William Choi is a surgeon with Neurosurgery Associates in Lone Tree, Colorado, and a BMI MAB contractor beginning no later than 2005. The Monday Report entries starkly demonstrate BMI's practice of soliciting doctors to become MAB contractors solely on the doctor's potential to use a high volume of BMI product. The Monday Report entries also demonstrate that many doctors would not begin using BMI products in performing surgery on their patient until BMI finalized their contracts.

8/21/05	Lost Business: "Dr. Choi. Jim is trying to set up a dinner. <i>Dr. Choi will average over 1.2 million per year-do we have any room for him??</i> "
8/28/05	New Business: "Dr. Choi PEEK mini and Dr. Castro peek and 3 Degree and SFS"
9/4/05	Lost Business: "Dr. Choi we have to get him more involved on a corp level I am trying to set up dinner @ NASS with Paul/Matt L."
9/18/05	Lost Business: "Will meet with Dr. Choi at NASS; this is very important!!! He is one of Biomets largest Docs\$\$\$."
10/23/05	Lost Business: "We lost Dr. Choi, however, we had a great meeting with him last Thursday and he is going to start to give us more cases. We are discussing an Advisory position with him. Look for this to close in the next few weeks. He is a big supporter of ICON and Hall"
10/30/05	New Business: " <i>Dr. Choi is ready to come aboard, however, we need to send him the paperwork. Dr. Choi is going to start to schedule Hallmark cases.</i> "
11/6/05	New Business: "Dr. Choi will start to use PEEK and Icon this month as well."
11/13/05	New Business: "Dr. Choi should start to schedule his cervical cases with us and some of his lumbar case w/peek we should get about 50-80 per month from his business he already scheduled 13 instrumented fusions this month."

12/25/05 Status Update: "Jim is trying to get Dr. Choi to speed up his Contract process with BMI; he is very slow in reviewing his contract. I told him it will expire in 15 days."

Emphasis supplied.

118. **Dr. Joseph Ciacci.** Dr. Joseph Ciacci is a surgeon at Spine Center at Sinai Hospital in Morton Mower, Maryland, and a BMI MAB contractor beginning no later than 2005. The Monday Report entries show clear ties between payments Dr. Ciacci received through his consulting agreement and the volume of BMI product Dr. Ciacci used in his surgeries. During the summer of 2005, after a contract compensation issue was resolved, Dr. Ciacci was "back on track using all products."

7/17/05 Status Update: "Matt Lyons and Bob Hastings need to sort out Dr. Ciacci agreement and re-define corrected compensation ASAP. Dr. C scheduled to be UPE surgeon for Construx Mini."

7/31/05 Status Update: "Dr. Ciacci contract still not rectified."

10/2/2005 Status Update: "NASS meetings/dinners set up for Drs. Davis, Khanna, Lemma, Sandhu, Rheing, Ciacci, Benalcazar, Sethi, Jacobson, Kuklo, Sylva."

10/23/05 Status Update: "Dr. Ciacci back on track using all products after MAB snafu's."

119. **Dr. Randy Davis.** Dr. Randy Davis is a surgeon with Mid-Atlantic Spine & Orthopedics in Glen Burnie Maryland, and an MAB from at least 2005 forward. The Monday Report entries show that Dr. Davis was targeted for a MAB position because he is considered a "leader" in the industry. Showing that BMI used consulting agreements as a front for paying loyal doctors, the regional manager urged Matt Lyons to quickly finalize the consulting agreement for fear of losing Dr. Davis' business. The Monday

Report reflect that immediately after becoming a BMI MAB contractor, Dr. Davis began to use BMI products in surgeries.

- 6/12/05 Status Update: "We need Matt L to follow up with Dr. Davis or we will miss opportunity to work with him, a leader in the industry."
- 7/10/05 Status Update: "Matt L please follow up with Dr. Davis to finalize this week."
- 8/7/05 Status Update: ***"Dr. Davis in agreement with MAB contract, will start cases late August."***

Emphasis supplied.

120. **Dr. Stewart Eidelson.** Dr. Stewart Eidelson, is a surgeon with Orthopaedic Surgery Associated, Inc., in Boca Raton, Florida. Beginning in 2004, BMI provided Dr. Eidelson with an "unrestricted education grant," comprising of an initial payment of \$1500 and at least \$500 dollars a month in support of his website for 12 months. When the educational grant expired in 2005, Dr. Eidelson contacted Relator Hutcheson and told her that he refused do surgeries with BMI products unless he received money. Hutcheson emailed Paul Sendro about the situation and he replied that he would "take care of it." Shortly thereafter, Hutcheson visited Dr. Eidelson's office with distributor Kelly Hill and Dr. Eidelson told her that if she did not get this situation straightened out, BMI would never see him again. In particular, Dr. Eidelson demanded that BMI "sponsor" his website. BMI shortly thereafter agreed to provide Dr. Eidelson with a \$1,000/month "sponsorship" for Dr. Eidelson's website. The following Monday Report entries reflect Eidelson's discontent:

- 6/12/05 Status Update: "Dr. Eidelson wants call from corp office this week, wants to discuss his contract and a visit to the home office."

6/19/05 Status Update: "Working on setting up meeting w Eidelson"

8/7/05 Status Update: "Kelly Hill in Wayne office with Dr. Eidelson"

8/14/05 Status Update: "Dr. Eidelson used Icon after his visit to the home office; case went well."

9/4/05 Status Update: "Chris has been talking w Paul, wants BMI to support Eidelson business"

9/11/05 Status Update: "Eidelson wants call from corporate and is very, very upset."

9/25/05 Lost Business: ***"Eidelson wants a contract and will not do cases unless paid."***

10/2/05 Status Update: "Chris trying to get Blumberg and Eidelson back."

Emphasis supplied.

121. **Dr. William Goodman & Dr. Todd Harbach.** Dr. William Goodman is a surgeon at St. John's Clinic –Orthopedic Specialists in Springfield, Missouri and a BMI MAB contractor beginning no later than 2005. Dr. Todd Harbach is a surgeon at the Spine Center and St. John's Medical Center in Springfield, Missouri and a BMI MAB contractor beginning no later than 2005. The Monday Report entries reflect the direct relationship between the scheduling of surgeries by the doctors and their continual payment as MAB's. Here, the regional manager urges BMI to get "someone" to tell Dr. Harbach that he needs to use more BMI product.

7/31/05 Status Update: "We need to have more communication with Harbach and Goodman!!! With Engineers; they feel neglected."

7/31/05 Status Update: "[L]ook for the following names to appear on the schedule of new business: ... Dr. Harbach. ***If we don't get cases from these drs I am going to look for new representation for MO. These guys have too many competitive lines.***"

- 8/21/05 Status Update: "I need someone to call Harbach to get him to support BSM products; he continues to ride the coat-tails of Dr. Bill Goodman. Please Help!!!!"
- 9/18/05 Lost Business: "Dr. Harbach and Goodman are sending in their letters of res next week. Duffy has done a poor job with communication and has lack of drive to get NEW business."
- 9/18/05: Status Update: "I really think there is a lack of interest with these guys, ***I am looking to replace them as well (A little house cleaning) as their numbers have dropped significantly.*** THEY ALSO PICKED UP ALPHA TECH; I think that's where Harbach and Goodman are going."
- 10/9/05 Lost Business: " We have lost Dr. Goodman and Dr. Harbach for lack of follow-thru. After Dave Neal³ left, the follow thru went down hill and we had no one to follow up with these guys on a regular basis."
- 10/23/05 Lost Business: "Dr. Harbach and Goodman are no longer a part of the BSM team (failed communication and lack of desire to return calls)"
- 10/30/05 Lost Business: "Dr. Wetherington and Harbach and Goodman."
- 11/6/05 Lost Business: "Dr. Harbach and Goodman: I think they are using Alpha Tech or Pioneer."

Emphasis supplied.

122. **Dr. Jaswinder Grover.** Dr. Jaswinder Grover is a surgeon at the Nevada Spine Institute in Las Vegas, Nevada. He was a BMI MAB contractor beginning no later than 2003. The Monday Report entries illustrate BMI's practice of having top BMI officials negotiate MAB consulting agreements. Robert Hasting, BMI's Vice President of Sales, personally negotiated Dr. Grover's contract. The entries show that BMI senior management was frustrated with Dr. Grover because they felt that he was not using enough BMI product. In January of 2006, Dr. Grover had begun using cervical devices manufactured by BMI competitor Interpore. Mr. Hastings was brought

back in to "revisit issues" with Dr. Grover.

6/26/05 Status Update: "Bob H. coming out to lock down contract of Dr. Grover."

7/3/05 Status Update: "Bob H. is coming out if early part of July to speak with Grover about MAB status."

7/17/05 Status Update: "Need to shore up MAB contract with Dr. Grover."

8/7/05 Lost Business: "Have lost cervical business from Dr. Kabins and Grover with 3 Degree."

9/4/05 New Business: "Need new Hallmark plate to make up for lost business with Kabins and Grover."

9/11/05 New Business: "Need new Hallmark plate to secure business from Kabins and Grover."

9/11/05 Status Update: "Would like to see if we can get Kabins or Grover to be on UPE for new Hallmark plate. We are not getting any Cervical business from them."

9/18/05 New Business: "Should start getting new ACDF business from Kabins and Grover with the Hallmark plate being in Vegas."

9/25/05 New Business: "Great Hallmark case with Kabins and Grover has 2 booked for this week."

9/25/05 Status Opportunity: "Huge opportunity to gain back lost cervical business from Grover and Kabins with the Hallmark plate."

1/1/06 Lost Business: "2 cases yesterday from Grover; he used Interpore cross on 2, 360 cervicals."

1/1/06 Status Update: ***"Will talk w/Bob H. this week to revisit issues w/Dr. Grover."***

Emphasis supplied.

123. **Dr. Kade Huntsman.** Dr. Kade Huntsman is a surgeon at Salt Lake Orthopedic Clinic in Salt Lake City, Utah and a BMI MAB contractor beginning no later

3 Dave Neal was a BMI engineer.

than 2003. The Monday Report entries show that Dr. Huntsman increased his use of BMI products immediately after negotiating his contract. The entries illustrate BMI's practice of using corporate pressure to get MAB contractors to use more BMI product.

- 9/4/05 Status update: "We met with Radd and Dr. Huntsman last week. ***Dr. H is happy with his agreement. Look to have him raise the level of cases in the next few weeks.***"
- 9/11/05 New Business: "Dr. Huntsman will schedule Hallmark cases this week."
- 10/2/05 New Business: "Dr. Huntsman tried the Hallmark plate and thinks it's a great plate. Eric and I will be scheduling a meeting with him to encourage him to support BSM more."
- 10/9/2005 Lost Business: "We have lost all MIS-I and 2-level cases to Nuvasive with Dr. Huntsman; he likes the dual ball rods they have. We have a dinner scheduled with him this week to address these issues and get things back on track. He will raise his level of BSM support this week."
- 10/23/05 Status Update: "Myself, Paul, and Eric have a dinner with Huntsman to discuss more support of BSM and some new ideas for Trinity. Dr. Huntsman is very interested in Trinity and we need to get him the ICON to evaluate along with our MIS distractors."
- 10/30/2005 New Business: ***"Dr. Huntsman is ready to roll; expect to see a 180 with his support.*** We also need to manufacture his new style peek and use it as it has MORE aggressive teeth and is wider. ***I will be spending more time with him and his family.*** He will also begin to use (hammer out Trinity)."
- 10/30/05 Status Update: "We need to keep the communication OPEN with Dr. Huntsman Radd is ready to drop Nuvasive. This is great because he will give us 110% of his focus on BSM."
- 12/4/05 Status Update: "Dr. Huntsman will attend the Trinity meeting in Chi town and needs to be VIP ed !! He needs a scheduled meeting for Trinity."
- 12/18/05 Status Update: "I will be attending the Trinity meeting with Dr. Huntsman and will try to discuss his support with BSM. I could use some assistance at the Trinity meeting from Matt or Billy."

Emphasis supplied.

124. **Dr. Simone Lavi.** Dr. Simon Lavi is a surgeon at Lavi Spine & Orthopedic Medical Center, Inc. in Encino, California. In late 2005, BMI undertook to recruit Dr. Lavi to become an MAB contractor. Monday Report entries show that Dr. Lavi was targeted because he was considered to be a high volume surgeon. Once he showed initial willingness to use BMI's products, BMI sought to "engage" Dr. Lavi as an MAB contractor to ensure his continued commitment to BMI product. Notably, BMI expected to see an immediate increase in Dr. Lavi's use of BMI products after he met with President Matt Lyons and his contract had been sent out. Moreover, reflecting the corporate model that paid contractor relationships are tied to a doctor's use of BMI products, the entries state that BMI must finalize Dr. Lavi's consulting agreement quickly, otherwise or risk losing Dr. Lavi's business to Alphtec, a competitor.

6/12/05	Status Update: "Working with Dr. Capen to go after Dr. Lavi. He is Pacific surgeon that is worth 60K monthly."
7/3/05	New Business: "Dr. Lavi has scheduled 1st ICON for July."
7/17/05	New Business: "Dr. Lavi did 1st ICON and SFS case last Friday and we will see more cases this month from him."
7/24/05	New Business: "1st G2 cases from Nelson done last week. Looking for additional cases from he and Capen this week. Lavi did 2 cases last Friday. Things are going well."
7/31/05	New Business: "Dr. Lavi did SFS case last week and Larsen did SFS case. <i>Need to capture new rep relationships to move forward.</i> "
8/7/05	New Business: "Dr. Simon Lavi did over 45K with us."
8/28/05	New Business: "Dr. Lavi is using our PLIF bone on Friday for the first time."
9/11/05	Status Update: "Lavi is doing majority of cases with us."

9/11/2005 New Business: "Need to get new G2 inserter ASAP. ***Lavi is starting to use us for all cases. We are leaving over 80K monthly in PLIF business on the table.***"

10/9/05 ***Status Update: "Dr. Lavi should be engaged."***

10/16/05 New Business: "Dr. Lavi performed case with Hallmark."

10/16/05 Status Update: "Contract is set to go to Lavi to be centered on Biologics."

11/6/05 ***Status Update: "Matt met w/Simon Lavi and these discussions will continue."***

11/13/05 ***New Business: "Should start seeing more cases from Dr. Lavi this month."***

11/20/05 Lost Business: "PLIF bone from Capen & Nelson and potential cases w/Lavi because of conflict he perceives in his contract."

11/27/05 Lost Business: "Lavi from contract ..."

11/27/05 Status Update: "Still working on resolving Lavi contract and issues he wants worked out."

12/4/05 ***Lost Business: "[P]otential cases w/Lavi because of conflict he perceives in his contract."***

12/4/05 ***Status Update: "Need contract issue w/Dr. Lavi resolved or we will lose him to Alphatec."***

12/11/05 Status Update: "Still need resolution to Dr. Lavi contract or to move on to new prospect."

12/25/05 Status Update: "Eric is following up with Dr. Lavi's request on MAB."

1/1/06 New Business: "CC bone used by Dr. Lavi."

1/1/06 ***Status Update: "Need to resolve issue with Dr. Lavi. Will speak with Eric H. regarding his MAB demands."***

Emphasis supplied.

125. **Dr. Michael Mason.** Dr. Michael Mason is a surgeon at Boston Arthritis

and Spinal Surgery in, Brookline, Massachusetts and a BMI MAB contractor beginning no later than 2005. Monday Report entries reflect that after negotiating his consulting agreement, Dr. Mason was using BMI products in all his surgeries. Moreover, the entries states that the surgeries were performed with BMI product “as promised” after the agreement was in place. Clearly, the purpose of the consulting agreement was to induce the surgeon to schedule more surgeries using BMI product.

6/19/05 Status Update: “Matt to follow up with Dr. Mason this week.”

6/26/05 Status Update: “Matt L. follow up with Dr. Mason to finalize relationship.”

7/3/05 New Business: “Dr. Mason has begun re-booking all his cases with Blackstone, no more Stryker!”

7/3/05 Status Update: “Dr. Mason booked 3 huge cases with us beginning on Monday. The proposed ALIF mono PEEK will meet his needs and add significant volume. Dr. Mason is also selected for the Unity UPE.”

7/31/05 Status Update: ***“Dr. Mason has been giving all cases to BMI as promised.”***

Emphasis supplied.

126. **Dr. Anise Mekhail.** Dr. Anis Mekhail is a surgeon at Parkview Orthopaedic Group in Palos Heights, Illinois and a BMI MAB contractor beginning no later than 2005. The Monday Report entries reflect BMI’s practice to “engage” a surgeon on a product to service their use of that product: “Need to find a place” for Anise Mikael on MIS/SCOLI!!!” The entries also show that after Dr. Mekhail refused to use BMI products in a surgery “due to no follow up from VPs,” the regional manager exhorted BMI senior Management to get a contract to Dr. Mekhail.

7/10/05 New Business: “Dr. White in Milwaukee, Scolio with Mikael”

7/10/05 Status update: ***“Need to find a place for ANISE MIKAEL ON MIS/SCOLI!!! PLEASE GET THIS DISCUSSED.”***

7/31/05 New Business: “Anise Mikael for Scoliosis cases for next week with SFS”

8/7/05 New Business: “Mekhail now doing big scoli cases with SFS; need instruments to get more.”

8/7/05 Status Update: *“Paul to call Mekhail on July 29th to discuss engaging him with Blackstone Medical”.*

8/14/05 New Business: “Mekhail new scoli cases with us”

8/21/05 Status Update: “Need paperwork draft to go out to Mekhail for MIS/Scoli team. The time is now.”

8/21/05 New Business: “New larger cases with SFS Mekhail”

8/28/05 Status Update: “Anise Mekhail, we need to get something out to him this week.”

9/4/05 Lost Business: *“Mikhail case last Friday due to no follow up from VP’s”*

9/4/05 Status Update: “Need to get something out to Anise Mekhail”

9/11/05 Status Update: “Also looking to get an agreement out to Anise Mekhail from Matt.”

11/6/2005 Status Update: “Expect Dr. Mekhail's signed agreement back next week.”

Emphasis supplied.

127. **Dr. Tim Peppers & Dr. Erik Westerlund.** Drs. Tim Peppers and Erik Westerlund were both surgeons at San Diego Orthopedic Medical Center in Encinitas, California. They were BMI MAB contractors beginning no later than 2005. The Monday Report entries demonstrate that BMI considered these two doctors to be crucial to increasing sales, and this was the impetus for negotiating consulting agreements with them. Reflecting BMI’s intent to induce MAB contractors to use a high volume of BMI

product during surgeries, the entries that Dr. Westerlund has started to use BMI product in most surgeries in anticipation of becoming an MAB contractor. Drs. Peppers and Westerlund however, were terminated when BMI noted that their use of products had decreased, and discovered in late 2005 that they were receiving payments from Alphatec, a competitor.

- 8/14/05 New Business: "Westerlund is booking more and more cases with us."
- 8/21/05 New Business: "Westerlund will have biggest month with us ever."
- 8/21/05 Status Update: ***"Walt is doing great job. In anticipation of his coming on board, Westerlund has shifted majority of cases to Blackstone. San Diego will do over 100K in revenue this month. We have tremendous opportunities for this region to be doing over 200K by end of year."***
- 9/4/05 Status Update: "We need to maximize Dr. Westerlund and Peppers exposure to Blackstone. These guys are key to San Diego territory. Both are being heavily courted by competitive companies. Would like to get both involved immediately in ALIF project."
- 9/11/05 Status Update: "We need to get Westerlund and Peppers involved in some design or product evaluation teams. They need to be the cornerstone for San Diego territory."
- 9/25/05 Status Update: "Getting more cases from Westerlund and Peppers. Still need to get them more involved in projects. Alphatec going after both of them hard."
- 10/9/05 Status Update: "Should have full month with Peppers/Westerlund."
- 11/6/05 Status Update: "Should have Trinity cases booked this month w/Westerlund & Peppers."
- 11/13/05 Status Update: "Peppers and Westerlund made up only 18% of business last month. They should have big month in November."
- 11/27/05 ***Status Update: "Found out Alphatec has offered money to Core center where Peppers and Westerlund are. They are going to hold courses there and have offered both surgeons to be design surgeons."***

12/4/05 Lost Business: "Cancellation of scoli case w/Peppers"

12/4/05 ***Status Update: "Need to discuss MAB relationships w/Peppers and Westerlund and their involvement w/Alphatec."***

12/11/05 New Business: "Talked with Peppers and Westerlund to gauge interest in continued relationship with Blackstone after Paz's departure and both surgeons will continue to work with us."

12/18/05 Lost Business: "Peppers huge scoli case lost due to patient."

1/1/2006 Status Update: "Dr. Peppers and Westerlund have been dropped as MAB surgeons as Friday, Dec. 24th."

Emphasis supplied.

128. **Dr. Michael Reed.** Dr. Michael Reed is a surgeon at Spinal Associates in Panama City, Florida and was an MAB from at least 2002 forward. The Monday Report entries show that Dr. Reed was re-negotiating his consulting agreement and was upset at lack of "corporate attention." BMI lost some of Dr. Reed's business to a competitor because a competitor got a contract to Dr. Reed before BMI finalized his consulting agreement. Dr. Reed was eventually terminated from his MAB contract because BMI was unable to produce the size of mesh product they had promised and he continued to use a competitor's product. In November 2005, he was presented with a new contract.

7/24/05 New Business: "Dr. Reed on vacation for 2 weeks in Mexico, but has 5 ICON cases the 1st week of August. ***He is upset with the lack of corporate attention.***"

7/31/05 Status Updates: "Dr. Reed on vacation; Paul will visit w Reed the first week of August."

8/7/05 Status Update: "Dr. Reed has been on vacation for the past 2 weeks; has 3 ICON cases scheduled this week Aug 2, 4 and 5. Paul will see him Wed night."

8/14/05 Status Update: "Paul, Susan & Jason met w Bill and Dr. Mike Reed. Dr. Reed will continue to use ICON, 3 degree, and cervical bone."

8/21/05 Status Update: "Dr. Reed using more BMI; he needs corporation attention every once in a while; using Icon 3 degree and cervical bone consistently."

8/28/05 Status Update: "Dr. Reed is increasing his use of BMI products."

9/4/05 Status Update: "Reed happy."

9/18/05 Status Update: "Trying to get Dr. Reed set up to meet with AI at NASS; he has a slow week this week."

10/2/05 Status Update: "Dr. Reed in meeting with AI and Paul at NASS."

10/9/05 Status Update: "Dr. Reed met w AI Lombardo at NASS and is very positive about moving forward w BMI."

10/16/05 Status Update: "Bill waiting for Dr. Reed's contract from Paul. I need to have Wingo meeting w Paul, since it didn't happen at NASS."

10/23/05 Status Update: ***Dr. Reed waiting on his contract before he will move forward on projects.***"

11/13/05 Status Update: "Reed contract sent for Friday delivery ..."

11/20/05 Status Update: "Dr Reed received his contract."

12/18/05 Status Update: "***Dr. Reed working w/Danek since they got a contract to him first; so his business with us has slowed down.*** He is doing cervical bone cases with them, since we can't supply 9mm."

Emphasis supplied.

129. **Dr. Howard Reichman.** Dr. Reichman is a surgeon at Utah Neurological Clinic in Provo, Utah, and a BMI MAB contractor from at least 2002 forward. Monday Report entries reveal that Dr. Reichman threatened to stop using BMI products when he became dissatisfied with his contract. Evidencing BMI's practice to funnel money to surgeons through the consulting agreements in exchange for use of

product during surgeries, Dr. Reichman demanded “a better package” from BMI and threatened to “move in a different direction” if his demands were not met.

- 9/18/05 Status Update: “Dr. Reichman has several Hallmark cases booked for next week. ***He will be coming out to PGH and I will be taking care of his needs...lots of fun and of course, Business.***”
- 10/2/05 Status Update: “I will be flying to PGH on Friday to meet Dr. Reichman to golf at Oakmont and entertain D Johnson and Dr. Bloomenthal [sic] Sunday. Dr. Reichman has given Hallmark strong praises!”
- 10/9/05 Status Update: “Dr. Reichman is very excited about the Hallmark and the changes on the cervical disc (see Al L)”
- 10/9/05 Status Update: “We had a great meeting in Pittsburgh and myself and Dr. Reichman have a great bond going.”
- 10/23/05 Status Update: “Paul and Eric are coming in to meet with Dr. Reichman this week to review new business and discuss his participation level with BSM.”
- 10/30/05 ***Status Update: “Paul and I met with Dr. Reichman Wednesday morning Dr. Reichman is not Happy with BSM He feels he has been with BSM and his work and time is not appreciated he wants a better package with Blackstone or he is ready to move in a different direction. His thoughts are he has helped BSM since the beginning since he does not make any noise (he is quite [sic]) his thoughts are set aside so please address these issues ASAP!!”***

Emphasis supplied.

130. **Dr. Jon White.** Dr. Jon White is a surgeon at Irvine Regional Hospital in Irvine, California and a BMI MAB contractor beginning no later than 2005. As the Monday Report entries reflect, BMI characterized Dr. White as a “very busy” surgeon and courted him for an MAB position. In anticipation of “contract in hand,” Dr. White ramped up his usage of BMI products, showing his loyalty to the company by putting up “big numbers.” Having secured that business, the sales representative reports,

“Continuing to prospect for more surgeons and support Dr. White.”

9/18/05	New Business: “Dr. White in Orange County has scheduled 3 ACDF.”
10/9/05	Status Update: “Dr. Jon White is scheduled to visit Wayne on 15th of month. Very busy Orange County surgeon.”
10/16/05	New Business: “Have Dr. Jon White scheduled for VIP visit on Friday.”
10/30/05	New Business” “Dr. Jon White did 35K scoli case last Wednesday. Had good things to say about system.”
11/6/05	New Business: “Dr. Jon White has scheduled 2 more cases with us this month. Hallmark and SFS.”
11/6/05	Status Update: “ Great meetings last week with Drs. White and Armstrong to shore up relationships.”
11/13/05	New Business: “Dr. White did 1st 3 degree with CC bone and it went very well. Has 2nd T-10/S1 case booked today.”
11/13/05	Status Update: “White and Kinchen, Coufal are starting to support more cases for us.”
12/4/05	<i>New Business: “Dr. Jon White should have contract in hand this week. Had 13, 3-degree cases in next few weeks.”</i>
12/4/05	<i>Status update” Jon White is putting up big numbers this month in cervical.”</i>
12/11/05	Status Update: “White has been extremely busy with cervicals past month.”
12/18/05	<i>Status Update: “Continuing to prospect for more surgeons and support Dr. White.”</i>
12/18/05	Status Update: “Have new targets in Dr. Muduyham and Ali who are in similar situation to Dr. Jon White.”
12/25/05	Status Update: “Cases being generated by Dr. White. His contract is signed and he seems pleased with it. Need to figure out bone solution for him for ALIF cases. We can capture significant business with his anterior approaches.”

1/1/06 Status Update: "Dr. White has big January booked."

Emphasis supplied.

131. **Additional Statements Regarding Close Nexus Between Payment and Referrals.** The following chart sets out additional statements reflecting that the purpose of BMI's arrangements was to induce the performance of surgeries using BMI products.

SURGEON	REGION	HOSPITAL	LOCATION	MONDAY REPORT EXCERPTS
Dr. Ardavan Aslie	NW	Rideout Memorial Hospital Sutter Roseville Medical Center	Marysville, CA	6/12/2005: New Business "Looking to bring on Nottingham (1.7mm) & Aisley (1.2mm). MAB Guys "A&B" Funding."
Dr. Mokbel Chedid, Dr. Patel	MW	Genesys Regional Medical Center Henry Ford Hospital	Detroit, MI	10/16/2005: Status Update "Need Chedid to be engaged for dynamic stabilization MAB." 10/30/2005 Status Update "Chedid to travel to New Jersey to visit Al Lombardo and Engineering on 11/4 for Dynamic Stabilization project." 11/6//2005 Status Update "Chedid to travel to New Jersey to visit Al Lombardo and Engineering on 11/4 for Dynamic Stabilization project." 11/13/2005 Status Update "Chedid to travel to New Jersey to visit Al Lombardo and Engineering on 11/4 for Dynamic Stabilization project." 11/20/2005 Status Update "Going to support a couple of surgeon dinners to increase referrals to Chedid, Patel." 12/11/2005 Status Update

SURGEON	REGION	HOSPITAL	LOCATION	MONDAY REPORT EXCERPTS
				<p>"Need Chedid to be engaged for dynamic stabilization MAB."</p> <p><u>12/18/2005 Status Update</u> "Need Chedid to be engaged for dynamic stabilization MAB."</p> <p><u>12/25/2005 Status Update</u> "Chedid sent agreement back with modifications"</p>
Cooper MC Neurogroup		Cooper University Medical Center	Camden, NJ	<p><u>7/10/2005</u> "Documentation that Dr. Linovitz and Diane Johnson requested for Cooper MC grant has been submitted to Celia Couture."</p> <p><u>7/17/2005</u> "Cooper MC/Neuro Group has submitted all required paperwork to Celia and Dr. Linovitz for Grant request to be completed at Exec meetings this week."</p> <p><u>8/21/2005</u> "Thank you Paul, Matt F, Diane, and Dr. Linovitz for adding Cooper to the Interbody study. This will work out well with the neuro group, and will help us gain more from the ortho side."</p> <p><u>8/28/2005</u> "Once again a reminder that Dr. Linovitz MUST provide Interbody Study commitment in writing to Cooper Mc neuros ASAP. This is a bad situation continuing to go south....."</p>

SURGEON	REGION	HOSPITAL	LOCATION	MONDAY REPORT EXCERPTS
Dr. Frank Coufal	PC	Fountain Valley Regional Hospital and Medical Center Alvarado Hospital Grossmont Hospital Scripps Memorial Hospital, La Jolla	La Jolla, CA	<u>8/7/2005: Status Update</u> "Dr. Kinchen and Coufal will continue to produce revenue with consulting agreement we have with Kevin Seeburg."
Dr. M. David Dennis	SW	South Texas Spine & Surgical Hospital Del Sol Medical Center	San Antonio, TX	<u>6/12/2005: Status Update</u> "Dr. Dennis' caseload for BMI has dropped; nearing end of his study." <u>6/19/2005: Lost Business</u> "Dr. Dennis to slow up on cases until we work out our future together." <u>8/7/2005: New Business</u> "Dr. Dennis committed more than ever. Waiting for Training contract!"
Dr. Jatinder Gill	NE	Massachusetts General Hospital Winchester Hospital	Boston, MA	<u>9/25/2005: New Business</u> "Meeting with Dr Gill was "interestin"- he led with wanting a consulting agreement. This seems to be becoming commonplace for new surgeons entering practice. Meetings with MAB's set up for NASS." <u>10/9/2005: Status Update</u> "Dr. Gill discussion for MAB will continue this week." <u>12/25/2005: Status Update</u>

SURGEON	REGION	HOSPITAL	LOCATION	MONDAY REPORT EXCERPTS
				"Dinner meeting with Dr Gill last week went well, he will become an Education Dept consultant."
Dr. Alexander Jones	MT	Exempla Saint Joseph Hospital	Aurora, CO	<p><u>7/24/2005: Status Update</u> "Cases with Dr Jones and Dr Schwarz. Dr Jones wants to do a study with the Hallmark; he will get all of his partners to use Hallmark (4) which will increase the numbers greatly!!"</p> <p><u>7/31/2005: Status Update</u> "I need to get Dr Jones a per diem."</p> <p><u>10/2/2005: New Business</u> "Dr Jones will be helping out with our advanced training in CHI town"</p> <p><u>10/9/2005: New Business</u> "Dr Jones is excited about his new role with the education dept and has scheduled a Hallmark plate for this week."</p> <p><u>10/16/2005: New Business</u> "We had good meetings with Dr Kurica and will have one during NASS to see where we are going with him. Dr Jones will be helping out with our advanced training in CHI tow"</p> <p><u>11/20/2005: New Business</u> "Dr Jones is excited about his new role with the education dept and has scheduled a Hallmark plate for this week.</p> <p>Dr Jones should be back in surgery next week."</p>

SURGEON	REGION	HOSPITAL	LOCATION	MONDAY REPORT EXCERPTS
Dr. Stanley Jones	SW	Memorial Hermann Southwest Bayou City Medical Center Foundation Surgical Hospital	Houston, TX	<u>7/24/2005: Status Update</u> "Dr. Jones to make a decision on what system he wants to use in a study this week!" <u>8/28/2005: New Business</u> "Dr. Jones schedules another case, looking for a research grant for a study." <u>8/28/2005: Status Update</u> "Opportunity with Dr. Jones, he is looking to do a study."
Dr. Melanie Kinchen	PC	Presbyterian Intercommunity Hospital Whittier Hospital Norwalk Community Hospital	Whittier, CA	<u>8/7/2005: Status Update</u> "Dr. Kinchen and Coufal will continue to produce revenue with consulting agreement we have with Kevin Seeburg."
Dr. Ken Kurica	MT	Centura Health-Penrose St. Francis Hospital Memorial Hospital of Colorado Springs	Colorado Springs, CA	<u>9/18/2005: New Business</u> "Dr Ken Kurica is ready to start using BSM out in Colorado Springs. This is great news as we have been courting his relationship for quite some time. Dinner date TBA maybe this week!!" <u>9/25/2005: New Business</u> "Dr Ken Kurica is ready to start using BSM out in Colorado Springs. This is great news since we have been courting his relationship for quite some time. Dinner date TBD maybe this week!! We have a meeting set up with Dr Kurica from CO Springs; he is ready to commit to BSM."

SURGEON	REGION	HOSPITAL	LOCATION	MONDAY REPORT EXCERPTS
				<p><u>10/16/2005: New Business</u> “We had good meetings with Dr Kurica and will have one during NASS to see where we are going with him.”</p> <p><u>11/20/2005: New Business</u> “Dr Kurica is waiting for a Letter of Confirmation regarding his participation in the Trinity project.”</p>
Dr. Phillip Lucas, Dr. Mark Palumbo, Dr. Ready	NE	Rhode Island Hospital	Providence, RI	<p><u>9/18/2005: Status Update</u> “Mike and Bill Lyons made the Patriots game a huge success with the surgeons, a mix of current users and new prospects. 3 new users are Drs Palumbo, Lucas, and Ready.”</p>
Dr. Mark McLaughlin	NE	Saint Francis Medical Center University Medical Center at Princeton Saint Mary Medical Center	Langhorne, PA	<p><u>10/16/2005: Status Update</u> “Dinner Monday night at CNS with Dr McLaughlin.”</p> <p><u>10/30/2005: Status Update</u> “Dinner meeting set up for Dr McLaughlin in 2 weeks. We will also discuss per diem work for his partner Dr Shah.”</p> <p><u>12/4/2005: Status Update</u> (for distributor Orthopaedic Sol) “Dr McGlaughlin will be at Eagles game with AI next week, committed to using NewBridge.”</p>

SURGEON	REGION	HOSPITAL	LOCATION	MONDAY REPORT EXCERPTS
Dr. Paul Nottingham	NW	John Muir Medical Center-Walnut Creek John Muir Medical Center-Concord Campus	Walnut Creek, CA	<u>6/12/2005: New Business</u> “Looking to bring on Nottingham (1.7mm) & Aisley (1.2mm). MAB Guys "A&B" Funding.”
Dr. Helson Pacheco-Serrant	SW	Providence Memorial Hospital Sierra Medical Center Sierra Providence East Medical Center Sierra Providence Rehabilitation Hospital The Children's Hospital at Providence	El Paso, TX	<u>9/18/2005: Status Update</u> “Dinner scheduled with Dr. Pachero at NASS.” <u>9/25/2005: Status Update</u> “Dinner scheduled with Dr. Pachero at NASS.” <u>11/6/2005: Status Update</u> “Dr. Pacheros, Dr. Bettincourt, Dr. Edonis interested in coming on board with Osiris. Metting scheduled this week.” <u>11/20/2005: Lost Business</u> “TRINITY sales from Dr. Pachero's generating good numbers. He is approved for the study.”
Dr. Saul Schwarz	MT	Exempla Saint Joseph Hospital	Denver, CO	<u>7/24/2005: Status Update</u> “Cases with Dr Jones and Dr Schwarz. Dr Jones wants to do a study with the Hallmark; he will get all of his partners to use Hallmark (4) which will increase the numbers greatly!!”
Dr. James Schwender	MW	Methodist Hospital Minneapolis	Minneapolis, MN	<u>9/18/2005: Status Update</u> “Looking to add an Education member from Treavor offer in this territory; either Dr. Schwender with Twin Cities Spine or Dr. Pera” <u>10/30/2005: Status Update</u> “Following up with Schwender

SURGEON	REGION	HOSPITAL	LOCATION	MONDAY REPORT EXCERPTS
				<p>this week for education consultant position; Treavor will try to meet with him while traveling.”</p> <p><u>11/6/2005: Status Update</u> “Need Ted to follow up with Schwender on Ed. MAB and schedule cases by November 4th or I am moving this opportunity elsewhere.”</p> <p><u>11/13/2005: Status Update</u> “Need ted to Follow up with Schwender on Ed. MAB and schedule cases by November 4th or I am moving this opportunity elsewhere.”</p> <p><u>11/20/2005: Status Update</u> “Not able to nail Schwender down to work on education position. Taking this opportunity away this week and going elsewhere in the territory. Ted will need to step it up soon. I am sending warning letter to him this week.”</p> <p><u>12/4/2005: Status Update</u> “Need ted to Follow up with Schwender on Ed. MAB and schedule cases by November 4th or I am moving this opportunity elsewhere.”</p>

SURGEON	REGION	HOSPITAL	LOCATION	MONDAY REPORT EXCERPTS
Dr. Charles Wetherington	MT	St. Anthony's Medical Center St. John's Mercy Forest Park Community Hospital	St. Louis, MO	<p><u>11/20/2005: Status Update</u> “Dr Wetherington used SFS on a L1 S1 case today and Jamy and I are still setting up an IMPORTANT meeting with Dr Wetherington. We have to get him on the expandable cage project ASAP; we owe it to him because he never has his hand out!”</p> <p><u>11/27/2005: Status Update</u> “Jamy has continued to stay in touch w/ Dr Wetherington and it looks as if all is moving in the proper direction with BSM. We need to put Dr Wetherington on the expandable cage project; he will not require a lot of attention, we just need to keep our lines of communication open.”</p> <p><u>12/4/2005: Lost Business</u> “Dr Wetherington-some of his SFS business; we need to make sure we get him on the Expandable cage project! This is a must he has been loyal to BSM for at least 3 years.”</p> <p><u>12/11/2005: Status Update</u> “Jamey and myself will attend a cervical surgery this week or next and get (Dr Wetherington) him on board with the expandable cage.”</p> <p><u>12/18/2005: Status Update</u> “I spoke to Jamy and it looks like we will bring Dr Wetherington on board for the expandable cage project. Dr W has been a long-time user of</p>

SURGEON	REGION	HOSPITAL	LOCATION	MONDAY REPORT EXCERPTS
				<p>BSM and requires little maintenance (\$\$ not looking for a hand out!). We need to keep the lines of communication open with Dr W. I will be flying in on the 28th to see a competitor's expandable cage being used in St Louis."</p> <p><u>12/25/2005: Status Update</u> "Looks like we should get Wetherington back in our camp once we get him involved with the expandable cage project. Burns was supposed to discuss the opportunity of getting all of his peek business."</p>
Dr. Mark Whitaker	MT	Kansas Surgery and Recovery Center	Wichita, KS	<p><u>6/19/2005: Status Update</u> "Dr Whitaker is continuing to support BSM; we need to give him a grant for his library."</p> <p><u>7/17/05: Lost Business</u> "Dr Whitaker is upset regarding his Honorarium and paid training sessions he held for his past and current BSM rep. It has been over 3 months and he has not received a check! He will be a large volume guy soon in W Kansas."</p> <p><u>7/24/2005: Status Update</u> "Dr Whitaker needs more attention."</p> <p><u>8/7/2005: Status Update</u> "Dr Whitaker needs to get a call from Corp and they need to give him a vote of confidence on his efforts regarding BSM breaking in to the Wichita, KS market."</p>

SURGEON	REGION	HOSPITAL	LOCATION	MONDAY REPORT EXCERPTS
				<p><u>8/21/2005: Status Update</u> “Dr Whitaker is continuing to support BSM; we need to give him a grant for his library. We are also setting up a VIP trip in SEPT and I will be in Wichita, KS next week as well trying to groom the relationship.”</p> <p><u>9/4/2005: Status Update</u> “Myself and Treavor will be having dinner with Dr Whitaker on Wed evening to discuss his role with education and eval of new products.”</p> <p><u>9/11/2005: Status Update</u> “Dr Whitaker got new education contact and is very pleased.”</p> <p><u>9/19/2005: New Business</u> “Dr Whitaker is very excited and happy that he is now involved with the education side of BSM; look for his input if anyone needs his participation.”</p> <p><u>9/25/2005: New Business</u> “Dr Whitaker is very excited and happy that he is now involved with the education side of BSM. Look for his input if anyone needs his participation.”</p> <p><u>10/2/2005: Status Update</u> “Dr Whitaker is very excited now that he is part of our education program; and he is looking to dig in deep with BSM”</p> <p><u>10/16/2005: New Business</u> “Dr Whitaker is very excited</p>

SURGEON	REGION	HOSPITAL	LOCATION	MONDAY REPORT EXCERPTS
				<p>and happy that he is now involved with the education side of BSM. Look for his input if anyone needs his participation. “</p> <p><u>10/20/2005: Status Update</u> “Dr Whitaker is very excited now that he is part of our education program; and he is looking to dig in deep with BSM”</p> <p><u>12/4/2005: Status Update</u> “Dr Whitaker needs to see all new products and we are trying to schedule a VIP trip to Wayne.”</p>
Armstrong, Ian		Cedars-Sinai Medical Center	Los Angeles, CA	<p><u>9/11/05: Status Update</u> “Armstrong is being wooed heavily by Globus and they are giving him 2 projects to work on. Need to get him involved in a corporate level and will work on something before NASS.”</p>
Levinthal, Robert		Providence Memorial Hospital Sierra Medical Center Sierra Providence East Medical Center Sierra Providence Rehabilitation Hospital The Children’s Hospital at Providence		<p><u>06/26/05 Lost Business</u> “Dr. Levinthal is working with Teken due to his son getting distributorship.”</p>

SURGEON	REGION	HOSPITAL	LOCATION	MONDAY REPORT EXCERPTS
Huntsman, Kade	MT	St. Mark's Hospital	Salt Lake City, UT	<u>6/26/2005 Status Update</u> "Dr. Huntsman is back in the camp as long as everything promised is followed through."
Vanichkocorn	SW		Houston, TX	<u>8/7/05 Status Update</u> "Dr V finally presented formal agreement from Treavor; very pleased. He will begin giving us all of his cases immediately."
	SE			<u>9/11/2005: Status Update</u> "Chris trying to find new MABs to increase business; he feels he has as much business as he can get and must have MABs to increase business."

C. THE MECHANICS OF BMI'S SHAM "ENGAGEMENTS"

132. The consulting agreements provided on their face that the MAB doctors would be "engaged" for a certain number of hours per month to consult on "projects" for BMI spinal products. In particular, a template Blackstone MAB contract dated October 2003 provides in section 1.1 that the

Consultant shall assist the Company in developing the Product, bringing it to market, and promoting its clinical use. To that end, Consultant shall provide the following services to and for the benefit of the Company for a minimum of ___ hours per month/quarter (circle one) during the Term hereof:

- (a) design and development support with respect to the Product,
- (b) clinical evaluation and/or scientific reporting of the Product, and
- (c) promotion of the Product through lectures and the provision of training services at locations specified by the Company after consultation with the Consultant.

133. These engagements were not conducted in the manner provided under the facial terms of the agreement. Rather, as demonstrated above, the actual purpose of the consulting agreement was to secure the MAB doctor's business.

134. In BMI parlance, to "engage" a surgeon to work on a "project" or to "develop" a product generally meant to pay the doctor to use the product in surgery and provide feedback to the sales representative who was present for every surgery as a matter of business practice. This paid "engagement" was aggressively sought by BMI, no matter how long the product had been in circulation or how many surgeons were already "engaged" on that product. This "engagement" was offered and paid notwithstanding that this service is something the surgeon already does in the normal course while performing surgeries and for which he or she is already paid by federal and private payors.

135. The sham nature of these engagements is best understood in the context of the timeline for the development and launch of BMI products, in which the opportunity for genuine assistance in the "development" of a product was extremely limited.

136. Most BMI products are based on a predicate device, a similar device that has already been legally marketed in the United States.

137. Predicate devices can be quickly approved by the FDA, and do not require the extensive research and development and clinical trial required of new device makers.

138. In order to approve a device for marketing, BMI submits to the FDA a Section 510(k) premarket notification of intent to use a predicate device (referred to as a

“510(k) application”). A 510(k) approval requires only that the device have “substantial equivalence” to a predicate device, and BMI must certify such in its application.

139. The FDA’s approval of the 510(k) application occurs within a relatively short time frame, typically within 3-4 months, as opposed to the many years that may be associated with bringing a new device to market.

140. The vast majority of products developed and launched by BMI have predicate devices⁴ and go through an expedited 510(k) process. This requires far less actual development, and greatly impacts the scope of consultant “projects” at BMI.

141. Attached as Appendix One is a listing of BMI products and their respective dates for 510(k) approval for marketing.

142. Given this shortened timeline, and the lack of extensive research and development for these copycat devices, there was only limited opportunity in which BMI could have reasonably engaged a surgeon to assist in the “development” of a product.

143. The process for the development and launch of BMI products is illustrated below, along with the areas in which a surgeon might be “engaged” in relation to such products:

- (a) BMI decides to develop and launch a new product based on a predicate device. BMI engineers are in charge of developing that product. The engineers design and build a prototype. BMI must produce a product demonstrating the substantial equivalency of the predicate device in order to get approval to market it.
- (b) At the design stage, an engineer might send drawings to a surgeon for

⁴ On information and belief, BMI’s artificial disc is the only product not based on a predicate device. BMI also has other products that do not require FDA approval, including laminated bone products (allograft, or bone harvested from cadavers) and the Trinity product (live tissue harvested from vertebral bodies in cadavers).

feedback on device or instrumentation design. Later, after a prototype is made, surgeon feedback may be requested from working with the instrumentation (simply handling the instrumentation) or using bone models (saw bones) to mimic the use of the device. Sometimes, this feedback is given during a cadaver lab using the device and instrumentation.

- (c) Biomechanical and wear testing is required by the FDA. BMI outsources this testing, usually using a lab, which puts the device through 5 million cycles of movement over a period of weeks.
- (d) Sterilization validation data is obtained and provided by BMI as part of the 510K application.
- (e) The 510K application is submitted to the FDA.
- (f) The FDA approval process generally takes approximately 90 days.
- (g) After the FDA approves the application, BMI has permission to begin marketing the device.
- (h) BMI generally launches a device as soon as possible after FDA approval. Generally, some product inventory is already ordered and on hand to start selling as soon as approval is obtained.
- (i) BMI generally starts with a "limited launch" of the product to a select group of surgeons. In that way, the surgeons with loyalty to BMI get to use product first, as many surgeons enjoy the privilege of being the first to use new technology or products. Additionally, if there were any initial problems with the product, a limited launch also limits knowledge of those issues to those with loyalty to the company.
- (j) After launch of the device, BMI may ask consulting and non-consulting surgeons for feedback on use of the product. A great deal of feedback is obtained in the normal course of business, such as by a distributor having a conversation with his surgeon customers during the performance of a surgery using the product.
- (k) BMI may engage a group of non-consulting surgeons to participate in a paid "study" of a new product after launch. Thus, sometimes BMI would be paying consultants for feedback on using the product and also be paying non-consultants per-diem fees for participating in a "study" on the use of a product.

- (l). BMI may ask a surgeon to provide input on a “Surgeon Technique Guide” that relates to the use of the product and instrumentation. These Guides are generally written by BMI personnel, and may also have input from consulting surgeons.
- (m) After launch, BMI may ask a consulting or a non-consulting surgeon to help market a product by being present at the BMI booth/table at annual conferences to answer questions about a product; or by demonstrating the use of a product in a cadaver lab sponsored by BMI (some surgeons were paid separately for this as a speaking engagement).
- (n) Separate from product-usage, BMI may also ask certain consulting surgeons to participate in sales representative training regarding the use of the product (there were training courses available once a month and WebX courses also became available).

144. Thus, while BMI routinely purported to engage myriad consultants on “projects” related to certain products, often years after the product was “developed” and launched, there were only limited areas where BMI might reasonably engage a surgeon to assist in product development. These areas include:

- Providing feedback to engineers on device or instrumentation design prior to 510(k) approval;
- Providing feedback on use of a product immediately post-launch, after 510(k) approval;
- Providing input in creating a “Surgeon Technique Guide” for use of a particular product;
- Providing education to sales representatives regarding the use of the product.

145. A surgeon’s input into the creation of a Surgical Technique Guide was likely limited, but did result in the surgeon’s name being on the guide. For the ICON system, for example, the guide was drafted by the product manager (Tom Primer) who sent a draft to Susan Hutcheson and to Dr. Paul M. Keller, for corrections or edits.

After some edits and a few sentence additions, the guide was published. Dr. Keller's name appears on the cover of the ICON Guide.

146. As referenced above, BMI occasionally asked a large number of surgeons to participate in "studies" of BMI products. These "studies" were not official clinical studies, but rather were used as a vehicle to attract new business. Thus, the study participants were generally not MAB doctors. The study participants were paid under a separate contract with BMI. Two such "studies" were put together in Relators' tenure:

- (a) The ICON study in mid-2005 was designed to target a potential image problem with the product. This modular pedical screw was similar to a device of Synthes, a competitor, which had problems with the head popping off the screw. Surgeons were concerned with the same problem with ICON, so BMI decided to have a "study" to demonstrate that the product did not have the same problems. The study participants were engaged under a contract with BMI and believed to have been reimbursed on a per diem basis.
- (b) The Trinity study was being marketed during the end of Relator Hutcheson's tenure at BMI. Trinity is a live tissue product which did not need FDA approval. BMI was trying to market it head-to-head with a similar product by Danek, Infuse. The "study" was an attempt to get part of that market and demonstrate to surgeons that BMI's product was competitive.

147. Thus, one would expect a limited number of surgeons to be engaged to provide feedback in discrete time frames before and after 510(k) approval of a product, which are listed specifically in Appendix One. However, that is not how consultants were engaged at BMI, because the primary purpose of the arrangements was to increase sales and induce the surgeons to increase their use of the product. Most surgeon feedback was use-oriented, and there were unreasonably high numbers of surgeons being "engaged" on all products for many years after the launch of the product.

148. For example, the following reflects surgeon “engagements” in 2005, based on BMI’s internal tracking document from July 2005 titled “Master Reference List” for MAB’s assigned to various products, along with a listing for ICON study participants in June 2005. As the chart illustrates, in 2005 alone, BMI regularly assigned multiple MAB doctors, purportedly to perform multiple hours of unspecified services on a single product that had already been developed and launched.

“Project” and 510(k) Approval Dates (where applicable)	Surgeon Assignments in 2005
<u>Allograft</u> (bone product) No 510(k) approval needed; Product used in surgeries since 1940’s; BMI started purchasing from vendor in at least late 2003	Daniel Capen (Biologics) Patrick Chan (Biologics) Richard Jordan (ALIF Biologics) Jaswinder Grover (ALIF Biologics) Russell Nelson (Biologics) Anthony Raben (ALIF Biologics)
<u>Ascent (P.O.C.T.S.)</u> 510(k) approval date in June 2003	Jaswinder Grover (Marketing) Bill Mastrodimos (Fixation R&D) Simcha Weller (Marketing, Fixation R&D)
<u>Biologics</u> (unspecified)	Nicholas Mataragas Ron Jon Paul (Fixation R&D)
<u>Cervical Disc</u> New device; not yet approved; Animal studies performed Europe 2005; Human studies beginning in 2008; FDA approval anticipated 2012	Scott Blumenthal (Biologics) Daniel Capen (Biologics) Patrick Chan Fernando Larraguibel (Int’l) Roberto Larrando (Int’l) Carlos Mourneir (Int’l) Russell Nelson (Biologics) Michael Nicolakis (Int’l) Daniel Pluis (Int’l) Robert Schoenmayr (Int’l) Luis Villota (Int’l) Robert Watkins, Sr. (Biologics) Lytton Williams (Biologics)
<u>Construx PEEK VBR</u> (Vertebral Body Replacement) 510(k) approval date in March 2004 Instrumentation and implementation redesign in approximately late 2005	Gregory Hoffman (Fixation R&D) Jeffrey Kozak (Fixation R&D) Mark Lorenz (Fixation R&D) Harvey Thomas (Fixation R&D) John William (Fixation R&D) Michael Zindrick (Fixation R&D)
<u>Construx (ALIF)</u> 510(k) approval date in March 2004 Instrumentation and implementation	Jeffrey Kozak (Marketing) Phillip Kravetz (Marketing) Timothy Peppers (Marketing)

“Project” and 510(k) Approval Dates (where applicable)	Surgeon Assignments in 2005
redesign in approximately late 2005	Harvey Thomas (Marketing) Erik Westerlund (Marketing)
<u>Construx Mini</u> (Line extension of Construx, small rhombus shaped spacer) 510(k) approval date in June 2005	Patrick Chan (Biologics) Marc Letellier (Biologics) Helson Pacheco (Biologics) Gary Schneiderman (Biologics)
<u>SFS/Deformity Project</u> SFS 510(k) approval date in February 2000; System additions in 2002; Minor engineering modifications in 2003; Deformity refers to SFS project, the Persuader instrument and hooks used with SFS. SFS line launched in 2002	Kevin Booth (Fixation R&D) William Goodman Todd Harbach (Fixation R&D) Kamel Ibrahim (Fixation R&D, Scoli) Paul Keller (Marketing) Michael Reing (R&D) Edward Shadeed (Fixation R&D)
<u>Fixation R&D</u> (unspecified)	Mark Kabins
<u>Grafx</u> (Osteoconductive Bone Graft Matrix) No FDA approval required; Licensed and supplied through third-party starting in approximately 2004	Mark Lorenz (Marketing) Michael Zindrick (Marketing)
<u>Hallmark</u> (Anterior Cervical Plate) 510(k) approval date in June 2005	Richard Jordan (Fixation R&D, Marketing) Helson Pacheco (Fixation R&D) Howard Reichman (Marketing)
<u>ICON</u> (modular pedicle screw) 510(k) approval date in October 2004; Pulled from the market in December 2005	Stephen Esses (Fixation R&D) Paul Keller Mark Lorenz (Fixation R&D) Alan McGee (Fixation R&D) Robert Watkins Sr. (Fixation R &D) Lytton Williams (Fixation R&D)
<u>ICON STUDY</u> Conducted June 2005	19 surgeons participated, including the following MABs: David Antezana Kevin Booth William Choi Joseph Grant Paul Keller Marc Letellier Mark Lorenz Tim Peppers Michael Reed Harvey Thomas Erik Westerlund

“Project” and 510(k) Approval Dates (where applicable)	Surgeon Assignments in 2005
<u>Marketing</u> (unspecified)	Mark Kabins
<u>Mesh</u> 510(k) approval date in June 2003	Ray Linovitz, (Fixation R&D) Michael Reed (Fixation R&D)
<u>MIS (Minimally Invasive System)</u> Not yet launched; In development stages in 2005	Daniel Bradley Mark Grub (Fixation R&D) Michael Hill (Fixation R&D) Todd Lanman Nicholas Mataragas (Fixation R&D) Ronjon Paul (Fixation R&D) Daniel Pluis (Int'l) Navinder Sethi (Fixation R&D) Robert Watkins Sr. (Fixation R&D, Marketing) Lytton Williams (Marketing)
<u>New Bridge (Laminoplasty)</u> 510(k) approval date in February 2005 Launched approximately May 2005	Kevin Booth (Fixation R&D, Marketing) Joseph Grant (Fixation R&D, Marketing)
<u>Unity</u> (Anterior Lumbar Plate) 510(k) approval date in June 2005	Adam Lewis (Fixation R&D, Marketing) Mark Caben
<u>Training</u> (Unspecified)	Hugo Benalcazar Renato Bosita Joseph Ciacchi Dan Cohen Janet Dunlap Jason Garber Kim Kee James O Neill Helson Pacheco James Rappaport Robert Rovner Susan Stephens Simcha Weller
<u>3 Degree</u> (Anterior Cervical Plate System) 510(k) approval date in June 1998; Modifications in 2002	Alan McGee (Fixation R&D, Marketing) Richard Ozuna (Fixation R&D, Training) Helson Pacheco (Fixation R&D) Reichman (Fixation R&D)

149. In a few cases, product instruments were refined after a product was launched based on surgeon feedback. However, the majority of products in Relators'

tenure did not require significant refinement after launch. In Ms. Hutcheson's tenure, the Construx VBR PEEK system was the only system that she recalls needing major instrument refinement.

150. In rare cases where a product failed or had problems, re-design or modification may have occurred, with the same sort of limited usage feedback as products needing refinement. The ICON system, for example, was redesigned after being removed from the market. The SFS system went through some modifications, as did the Construx PEEK VBR and Unity systems. The laminated bone product, not regulated by the FDA, was breaking in early 2004 due to design problems and another design was acquired from different vendors (bone is harvested from cadavers and acquired from tissue vendors).

151. Examples of surgeons purportedly "engaged" on products long after they were launched, and in a commercially unreasonable manner, are set forth below.

152. **Dr. Scott Blumenthal.** Dr. Scott Blumenthal is a surgeon at the Texas Back Institute in Plano, Texas. He was a BMI MAB contractor from at least 2002 forward. The 2005 Master Reference Documents state that he was assigned to work on the cervical disc project in the Biologics Department.

153. The cervical disc project was an ongoing project which began before Relator Hutcheson was hired by BMI. Because no predicate device was on the market until July 2007, BMI had to go through the IDE (Investigational Device Evaluation) process in order to market a cervical disc. The IDE process takes years to complete and requires clearance from the FDA to initiate the process in the United States. BMI

must complete animal studies, human studies, and a one year follow-up. BMI had started animal studies in Europe in late 2005. Orthofix, Inc. is currently sponsoring the government clinical trials within the United States which were launched in March of 2008, and estimated to be completed in March of 2012.

154. There was limited substantive consulting work that Dr. Blumenthal could have legitimately performed on the cervical disc project during 2005. Surgeons were not generally involved in pre-launch testing, such as biomechanical testing or animal studies. Instead, most surgeon feedback was use-oriented. Dr. Blumenthal's contributions would have been limited to oral feedback on drawings/prototype or instruments, or feedback on the instruments or any prototype, which likely would not have been available at this time frame. In 2005, the cervical disc was not being implanted and did not reasonably support 16.5 hours of consulting work each month from Dr. Blumenthal. And in fact, BMI's internal records, show that Dr. Blumenthal did not perform 16.5 hours per month on the cervical project or any other project. The Department Hour chart for November 2005, list Dr. Blumenthal as completing just 10 hours of consulting work (one hour on professional relations; 5 hours on marketing projects and 4 hours on research and development) for those months. Dr. Blumenthal did not complete any consulting hours in December of 2005.

155. Dr. Blumenthal was not the only surgeon assigned to work on the cervical disc project in 2005. The MAB Master Reference List reflects that 12 more doctors were assigned to work on the project in 2005. The fact that BMI assigned such a great number of doctors to work on a project during a period of time when there was clearly

little work available, illustrates that BMI selected and paid MABs without regard to legitimate needs.

156. **Dr. Kevin Booth.** Dr. Kevin Booth is a surgeon at the Northern California Spine Institute in Pleasanton, California and a BMI MAB contractor from at least 2003 forward. In 2005 Dr. Booth generated \$729,728 in sales for BMI, and was the 15th highest ranked surgeons for sales in the entire company.

157. The 2005 Master Reference Document reflects that Dr. Booth was assigned to work on the New Bridge and Deformity projects in the Fixation R & D department, and on the Laminoplasty Plate project with the Marketing department. Based on the November and December Department Hour charts, Dr. Booth was contracted for five monthly engagement hours and a total of 100 contract hours.

158. However, Dr. Booth's status as an MAB was clearly not contingent on performance of the hours he promised to deliver, as he failed to complete a single hour of work during these two months.

159. BMI kept Dr. Booth on as an MAB contractor despite the fact that he was not fulfilling his contracted hours, and instructed regional managers not to give Dr. Booth consulting work. On December 15, 2005, Ilisa Rosselli, assistant to Vice President Robert Hastings, sent an e-mail to the regional managers stating: "Please don't forget that we are still not engaging Drs Booth, Grant & Shadeed (If you must-please talk to Bob first!)."

160. **Dr. Renato Bosita.** Dr. Renato Bosita was surgeon at Texas Back Institute in Plano, Texas and a BMI MAB contractor doctor from at least 2003 forward.

161. In 2005, Dr. Bosita generated \$314,146 in sales for BMI, and was ranked the 42nd highest for sales in the entire company.

162. The 2005 Master Reference Document reflects that BMI assigned Dr. Bosita to the Training Department, without reference to any specific product. Based on the November and December Department Hour charts, Dr. Bosita was contracted to perform 7.5 hours of consulting work a month. However, in November 2005 he is listed as performing only 3 hours, in the area of “professional relations” which was unrelated to his training department assignment. In December 2005, Dr. Bosita did not complete any MAB hours.

163. Because a purpose of the consulting agreements was to pay doctors to use BMI products, BMI often assigned MABs to departments with no specific projects or plan for how the MAB would fulfill the contracted hours. MAB doctors that were not engaged in any legitimate were often generically assigned to “training” or “marketing.”

164. **Dr. Daniel Capen.** Dr. Daniel Capen is a surgeon at the Office of Daniel A. Capen, M.D. in Oxnard, California and was a BMI MAB from at least 2003 forward. In 2005, Dr. Capen generated nearly half a million dollars in sales for BMI and was ranked 25th highest for sales in the entire company. The 2005 Master Reference Document reflects that he was assigned to work on the allograft and Cervical Disc devices in the Biologics Department. Based on the November and December 2005 Department Charts, he was contracted for 5.5 engagement hours per month.

165. There was little substantive consulting work that Dr. Capen could have performed in 2005 on cervical disc in conjunction with the other 12 surgeons assigned.

Little consulting work on the cervical disc was needed in 2005 since BMI was in the midst of pre-launch animal studies in Europe. Likewise, BMI had little need for additional consulting work on the allograft product in 2005. Allograft is a bone/tissue product that is not regulated by the FDA, and therefore does not have to be approved through the 510k process for sale and use. Surgeons have been have been implanting allograft in spinal surgeries as early as 1942, and regularly for more than 30 years. BMI has sold various types of allograft products since at least late 2003, including ALIF (anterior lumbar interbody fusion), PLIF (posterior lumbar interbody fusion). In 2004, BMI renamed this group of products "AlloQuent."

166. BMI's AlloQuent products have always been designed and obtained by outside vendors. When initially launched to a select group of surgeons in late 2003 and 2004, BMI's designs for the cervical allograft and PLIF allograft were different from and noticeably inferior to the long-standing designs on the market. They immediately started breaking operatively and postoperatively. BMI quickly obtained new versions of these products from different vendors in more traditional designs and relaunched the product. Since BMI obtained their allograft product from outside vendors, MAB's were not needed to consult on the design of this product. Moreover, outside of the feedback obtained during the limited release of the first designs of BMI's AlloQuent line, and the acquisition of new designs immediately thereafter, there would have been little need for consultant hours. Moreover, by 2005 most of the upfront research on allograft systems, such as research on the healing rate of bone, had already been completed. Thus, there were very little consulting services for any surgeons to reasonably perform

regarding allograft products, other than using the bone during surgery and offering feedback.

167. The AlloQuent products, therefore, could not have provided Dr. Capen with adequate consulting work for 5.5 hours per month, and BMI's internal records show that Dr. Capen in fact did not fulfill his contracted hours. In November of 2005, Dr. Capen is listed as performing only three hours of consulting work (one hour in Biologics and two hours in marketing). In December of 2005, Dr. Capen did not complete any consulting hours.

168. Numerous other doctors were also assigned to work on the allograft products in 2005. The 2005 MAB Master Reference List reflects that five other doctors were assigned to work on this product in the Biologics Department. The fact that BMI assigned numerous doctors to work on a project during a period of time when there was clearly little consulting work reasonably available, shows that BMI selected and paid MABs without regard to legitimate needs.

169. **Dr. Bryan George.** Dr. George is a surgeon in New Orleans, Louisiana and was a BMI MAB contractor from at least 2003 to 2004. Dr. George provides a clear example of BMI paying an MAB contractor who had not performed any consulting work. Relator Hutcheson once visited with Dr. George at his office during her employment. During that visit, Dr. George complained that he had telephoned Vice President Robert Hastings numerous times to discuss what project he was supposed to be working on and could not get a return call. Dr. George had no assignments, and he was uncomfortable receiving a check from BMI without performing any consulting work.

Relator Hutcheson contacted Mr. Hastings about the situation, and he indicated that he “would take care of it.” Upon information and belief, Dr. George was not given legitimate consulting work, and BMI terminated his consulting agreement in 2005.

170. **Dr. Jaswinder Grover:** Dr. Jaswinder Grover is a surgeon with Nevada Spine Institute in Las Vegas, Nevada, and a BMI MAB contractor from at least 2002 forward. In 2005, Dr. Grover generated nearly \$1,000,000 in sales for BMI and was ranked eighth highest in sales in the entire company. The 2005 Master Reference Document reflects that Dr. Grover was assigned to work on the Ascent product in the Marketing and Biologics Departments. Based on the November and December Department Hours charts for 2005, Dr. Grover was contracted to perform an incredible 21 hours of consulting work per month, with a total of 250 total hours.

171. Neither the Biologics product (which include the allograft “AlloQuent” line and Trinity product) nor the Ascent product could have provided Dr. Grover with 21 hours of consulting work per month in 2005. Surgeons have been implanting allograft products for more than 30 years. BMI obtained all its AlloQuent products from outside vendors. By 2005, most of the upfront research on allograft systems, such as research on the healing rate of bone, had already been completed. Thus, there was no need for development of this product in 2005 and the most Dr. Grover could have been doing with this product was using it during surgery and offering feedback to the BMI. Moreover, multiple other MAB doctors were also assigned to consult on allograft products during this time.

172. The other Biologics or “bone” product that BMI offered in 2005 was Trinity, a putty derived from viable stem cells harvested from cadavers. Like the AlloQuent line, Trinity does not require FDA approval. Trinity was developed by an outside company, Osiris, and simply purchased by BMI to sell. Therefore, BMI would not have needed Dr. Grover’s consultation on the development of this product.

173. Dr. Grover’s other assignment was to BMI’s Ascent product, Ascent/P.O.C.T.S. This product was launched in late 2003 and early 2004 with little refinement to the product. While Dr. Grover could have provided pre-launch feedback in 2003, BMI had no need for him to consult on this product in 2005.

174. Clearly the already developed Biologics and Ascent products could not have provided Dr. Grover with legitimate consulting work to fulfill 21 hours per month. Indeed, BMI’s records clearly show that in November 2005, he did not complete any of his 21 monthly engagement hours. In December 2005, Dr. Grover is listed as performing only nine hours of consulting work (six hours in public relations and three hours on marketing.)

175. **Dr. Marc Letellier.** Dr. Marc Letellier is a surgeon at Southwest Center for Neurological Surgery in Mesa, Arizona and a BMI MAB from at least 2003 forward. In 2005, Dr. Letellier generated \$1,691,697 in sales for BMI and was ranked first for highest sales for BMI. The 2005 Master Reference Document lists him as assigned to work on the Construx PEEK Mini project in the Biologics Department. Based on the November and December 2005 Department Hours chart, he was contracted for an incredibly high 25 monthly engagement hours, and a total of 300 contract hours.

176. The Contrux PEEK Mini product would not have provided Dr. Letellier with 25 hours of legitimate consulting work per month. This product received 510(k) approval in mid-2005, but was only a line extension of the existing system. It was simply a smaller version of the rhomboid-shaped spacer for use between the vertebral bodies and would not have required much refinement, much less substantive consultant activity. While it is possible that Letellier provided feedback on the PEEK spacer in late 2003 and early 2004, and on the modification of the instrumentation/ implant in late 2005 and early 2006, there clearly was not enough activity related to PEEK in 2005 to justify 25 hours per month.

177. Dr. Letellier's high monthly engagement hours are also inconsistent with his sales volume. The hours he spent in surgery to use nearly \$1.7 million dollars worth of BMI's surgical product would have made it extremely difficult for him to consistently fulfill his 25 hours per month of consulting work. Indeed, the November and December Department Hour Charts reflect that while in November of 2005, he completed 23 hours on an unspecified marketing project, in December of 2005, Dr. Letellier did not complete any hours.

178. **Dr. Paul Schmitz.** Dr. Paul Schmitz is a surgeon at Medical Center Clinic in Pensacola, Florida, and a BMI MAB contractor from at least 2002 through early 2004. Like Dr. George Dr. Schmitz's situation also provides a clear example of BMI paying an MAB doctor who had not performed any consulting work. Relator Hutcheson visited Dr. Schmitz at Sacred Hearts' Hospital in Pensacola, Florida in early 2004. During that visit, Dr. Schmitz told Relator Hutcheson that he was uncomfortable with his MAB

arrangement with BMI because no one had contacted him to do any consulting work and he believed that he was being compensated for doing nothing. He expressed to Relator Hutcheson that he did not want to continue as an MAB, because there was no actual consulting work, and because of the government's scrutiny of the industry. Upon information and belief, Dr. Schmitz simply allowed his contract to expire with BMI.

D. MAB SERVICES WERE LARGELY UNDOCUMENTED AND THE HOURLY REQUIREMENTS WERE A SHAM

179. BMI paid MAB contractors monthly stipends without regard to whether they provided services or not, because the purpose of the arrangement was to obtain and retain their business. Put another way, it was entirely up to the individual physician whether or not she or he provided services.

180. Because BMI wholly failed to require the performance of actual commercially reasonable services in exchange for fair market value payment, BMI also failed to document the number of hours “engaged” by the MAB doctors.

181. The lack of this documentation merely illustrates the sham nature of its agreements.

182. The nature of BMI’s documentation system failures changed over time. In early 2004, when Ms. Hutcheson first started with BMI, Vice President Robert Hastings had delegated the job of documenting their work product to his assistant, Dagmar Polk. Sometime later in 2004, Ms. Polk left BMI and was replaced by another individual, Monique Distasi.

183. On information and belief based on Relators' observations during their employment, there was no formal system for surgeon time documentation prior to 2004. Moreover, as described below, between 2004 and 2005, there was no system that involved the sales team, who were and remained the primary contacts with the surgeons.

184. In a July 2004 sales meeting, Vice President Hastings made a presentation to the sales managers regarding the number (at that time, 48) and location of MAB contractors. Mr. Hastings indicated that a training manual for his new Executive Assistant was currently being finished and that the "Surgeon Consulting Reimbursement Form has been revised to show hourly consulting activity."

185. In 2005, a decision was made to shift responsibility for documenting time to the physicians themselves. MAB contractors were asked to submit an invoice for their monthly consulting fee. When most MAB contractors largely did not comply with this, the regional managers were tasked to call the MAB contractors to remind them to submit their invoices. When this system also failed, BMI attempted to implement a system where the surgeons were only paid for time submitted on invoices. This system, which resulted in surgeons not receiving payments, was met with the immediate discontent of the surgeons, some of whom reduced or discontinued use of BMI products. This gained the immediate attention of BMI, and the documentation system was changed yet again. Thereafter, it became the distributor's responsibility to assist the surgeons in filling out the form and to obtain their signature on the form.

186. On November 14, 2005, Mr. Hastings held a “Medical Advisory Board Consulting Training” session with BMI employees and discussed inadequate documentation practices. According to a PowerPoint training document used in the meeting reporting “accuracy” was necessary because of, among other things, the “Justice Department” and “Exposure.” BMI’s new “medical surgeon consulting system” directed the sales team to use Outlook to access a journal entry system for documenting time. This system directed the sales team to enter start and stop times for “engagements” with MABs, which appear to include all types of interactions with MAB’s regarding their observations of BMI’s product.

187. The MAB contracts were never distributed to the sales managers or distributors despite the fact that the sales team became responsible for “engaging” the MAB doctors on projects in order to meet the MAB’s contracted number of hours.

188. In late 2005, the regional managers began to receive monthly reports of “Department Hours,” indicating the number of hours each MAB was contracted versus the number of hours each MAB was engaged.

189. Reports for November and December of 2005 reflect that *not a single MAB contractor met his or her contracted hours*. The following charts reflect the hours reflected on BMI’s “Department Hours” charts for that time frame:

November 2005 Department Hours

Surgeon Name	Monthly Engagement Hours	Contract Hours	Assigned Project(s)	Hours Completed	Total Hours Completed
Hugo Benalcazar	8.5	100	R &D	2	

Surgeon Name	Monthly Engagement Hours	Contract Hours	Assigned Project(s)	Hours Completed	Total Hours Completed
			Marketing	4	6
Scott Blumenthal	16.5	160	Professional Relations	1	
			Marketing	5	
			R &D	4	10
Kevin Booth	5	100	None indicated	0	0
Renato Bosita	7.5	60	Professional Relations	3	3
Daniel Capen	5.5	65	Marketing	2	
			Biologics	1	3
Joseph Ciacchi	8.5	100	Marketing	2	2
Chicago Spinal Consultants (Mataragas &Paul)	8.5	100	R &D	1	1
Randy Davis	7	80	None indicated	0	0
Stephen Esses	7	80	Professional Relations	1	1
Jason Garber	7	120	Training	15	15
Joseph Grant	5	100	None indicated	0	0
Jaswinder Grover	21	250	None indicated	0	0
Michael Hill	5	100	Marketing	4	4
Gregory Hoffman	12.5	150	Professional Relations	4	
			Marketing	4	
			R &D	4	12
Kade Huntsman	8.5	100	Marketing	3	
			R&D	4	7
Kamil Ibrahim	8.5	100	Professional Relations	2	
			R&D	4	6
Richard	10	100	R &D	2	2

Surgeon Name	Monthly Engagement Hours	Contract Hours	Assigned Project(s)	Hours Completed	Total Hours Completed
Jordan					
Kee Kim	2.5	90	None indicated	0	0
Phillip Kravetz	7.5	89	None indicated	0	0
Todd Lanman	5	40	Professional Relations	1	1
Mark Letellier	25	300	Marketing	23	23
Mark Lorenz	17	200	Professional Relations	3	
			Training	5	8
Michael Mason	20	240	R & D	6.5	6.5
Anis Mekhail	8	Not indicated	None indicated	0	0
Russell Nelson	5.5	65	Professional Relations	1	1
James O'Neill	7	80	None indicated	0	0
James Olsen	12	144	None indicated	0	0
Richard Ozuna	8.5	100	Marketing	2	
			R &D	2	
			Training	4	8
Helson Pacheco	16	190	Marketing	12.5	12.5
Timothy Peppers	8.5	100	Professional Relations	1	1
Anthony Raben	3.5	40	None Indicated	0	0
James Rappaport	7.5	90	Training	1	1
Michael Reed	8	96	R &D	0.5	0.5
Howard Reichman	8.5	100	Marketing	3	
			R &D	2	5
Michael Reing	7	80	R&D	9	9

Surgeon Name	Monthly Engagement Hours	Contract Hours	Assigned Project(s)	Hours Completed	Total Hours Completed
Reynold Rimoldi	7	80	None indicated	0	0
Robert Rovner	14.5	86	None indicated	0	0
Navinder Sethi	8.5	100	Marketing	4	
			Training	1	5
Susan Stephens	7	80	Training	5	5
Harvey Thomas	20	250	Marketing	10	
			R&D	4	14
Robert Watkins Jr.	7	100	Professional Relations	1	
			Marketing	5	6
Simcha Weller	8.5	100	Marketing	1	1
			Training	3	6
Erik Westerlund	8.5	100	Professional Relations	4	
			Marketing	4	8
John Williams	12.5	150	Marketing	6	
			R &D	4	10
Michael Zindrick	11	380	None Indicated	0	0

December 2005 Department Hours

Surgeon Name	Monthly Engagement Hours	Contract Hours	Assigned Project(s)	Hours Completed	Total Hours Completed
Hugo Benalcazar	8.5	100	R &D	0.5	0.5
Scott Blumenthal	16.5	160	None indicated	0	0
Kevin Booth	5	100	None	0	0

Surgeon Name	Monthly Engagement Hours	Contract Hours	Assigned Project(s)	Hours Completed	Total Hours Completed
			indicated		
Renato Bosita	7.5	60	None indicated	0	0
Daniel Capen	5.5	65	None indicated	0	0
Joseph Ciacci	8.5	100	None indicated	0	0
Chicago Spinal Consultants (Mataragas & Paul)	8.5	100	Biologics	6	6
Randy Davis	7	80	R & D	2.5	2.5
Stephen Esses	7	80	None indicated	0	0
Jason Garber	7	120	R & D	4	
			Training	8	12
Joseph Grant	5	100	None indicated	0	0
Jaswinder Grover	21	250	Professional Relations	6	
			Marketing	3	9
Michael Hill	5	100	Professional Relations	5	5
Gregory Hoffman	12.5	150	Biologics	2	
			R & D	2	4
Kade Huntsman	8.5	100	Professional Relations	1	
			Marketing	3	
			Biologics	2	
			R&D	1	7
Kamil Ibrahim	8.5	100	R&D	8	8
Richard Jordan	10	100	R & D	3	3
Kee Kim	2.5	90	None indicated	0	0
Phillip Kravetz	7.5	89	Professional Relations	0.5	0.5

Surgeon Name	Monthly Engagement Hours	Contract Hours	Assigned Project(s)	Hours Completed	Total Hours Completed
Todd Lanman	5	40	None indicated	0	0
Mark Letellier	25	300	None indicated	0	0
Mark Lorenz	17	200	Professional Relations	0.5	0.5
Michael Mason	20	240	Professional Relations	1	
			Biologics	5	
			R &D	2	8
Anis Mekhail	8	Not indicated	None indicated	0	0
Russell Nelson	5.5	65	None indicated	0	0
James O'Neill	7	80	None indicated	0	0
James Olsen	12	144	None indicated	0	0
Richard Ozuna	8.5	100	Biologics	7	
			R & D	1	8
Helson Pacheco	16	190	None indicated	0	0
Timothy Peppers	8.5	100	Marketing	2	2
Cyril "Anthony" Raben	3.5	40	Professional Relations	1	1
James Rappaport	7.5	90	Biologics	7	7
Michael Reed	8	96	R &D	9	9
Howard Reichman	8.5	100	None indicated	0	0
Michael Reing	7	80	None indicated	0	0
Reynold Rimoldi	7	80	None indicated	0	0
Robert Rovner	14.5	86	Training	8	8

Surgeon Name	Monthly Engagement Hours	Contract Hours	Assigned Project(s)	Hours Completed	Total Hours Completed
Navinder Sethi	8.5	100	Marketing	2	
			R & D	0.5	2.5
Susan Stephens	7	80	None indicated	0	0
Harvey Thomas	20	250	Marketing	8	8
Robert Watkins Jr.	7	100	None indicated	0	0
Simcha Weller	8.5	100	Marketing	3	
			Training	3	6
Erik Westerlund	8.5	100	Professional Relations	3	
			Marketing	2	5
John Williams	12.5	150	Professional Relations	2	
			Biologics	2	
			R &D	1	5
Michael Zindrick	11	380	Biologics	6	6

190. The existence of hours reported on these charts does not demonstrate that commercially-reasonable work was performed. Much of the surgeon's services related to feedback or conversations regarding their paid performance of surgeries using BMI product.

191. BMI knowingly paid MAB contractor stipends notwithstanding the consistent failure to "engage" the MABs for the purported number of contract hours.

192. Emails were routinely circulated looking for additional engagements for MAB doctors and for additional hours to report for each MAB doctor. For instance, an October 19, 2005 Email from Monique Distasti to Brian Dukate, Robert Hastings, Ilisa

Rosselli titled "RE: Journal Entry Dr. Mataragus/ Dr. Paul Naperville, IL" states: "I am looking for October entries please. Mataragas and Paul good for Oct/. Hoffman, Jordan, Ibrahim, Lorenz, O'Nei I [sic], Raben, Stephens, & Zindrick, ALL need to be engaged for Oct ASAP!"

193. Responding to Ms. Distasti's email, Mr. Dukate indicated that Dr. Hoffman was "engaged" on 10/14 on the "3 Degree issue." Ms. Distasi replied that Dr. Hoffman needed to more hours. Mr. Dukate responded with the following agitated email to Vice President Paul Sendro:

Paul,

This is ridiculous! This is sucking up all of my time to the point that I cannot get anything else done!! Why are the other departments not engaging the MAB's. I cannot just make things up out of thin air and my reps getting back to me makes it even more impossible. We have gone from this being to write up a conversation you or a rep had with a surgeon to we don't have enough hours. Help! Vivian please make sure Paul gets this.

194. Since there was not enough legitimate work for all of the MAB doctors, BMI regularly padded hours, and counted feedback gained in the ordinary course of business as "consulting" services.

195. As a matter of general practice, time was rounded up; ten minutes, for example, could be reported as a 30 minute segment. In fact, BMI instructed its employees during a November 14, 2005 PowerPoint training on time keeping for MAB doctors that journal entries had to be made in at least 30 minute increments.

196. BMI also instructed its distributors and managers to count almost any interaction with an MAB doctor as "consulting" services. The "hours" documented by

the sales team were often had nothing to do with consulting services on assigned projects, but was simply a record of the time spent during a sales call, including those where the sales representative was observing the use of the product during surgery.

197. For example, a November 30, 2005 email from Monique Distasi, assistant to Vice President Robert Hastings, titled "Consulting Topics/Guidelines" clearly shows that BMI encouraged distributors to count any general feed-back from an MAB doctor regarding BMI products while performing a surgery as "consulting" activity. Ms. Distasi wrote that "General MAB topics of discussion during an O.R. visit" can include, among other things,

- "Whatever is on the MAB's Consulting Agreement of Responsibility, (OBVIOUSLY!);

As well as such questions, among others, as:

- "Tell me about the ease of use with the instrumentation.";
- "How can BMI better serve your O.R. staff?"
- "What can BMI do to Improve it's Marketing Department?"

198. Likewise, many distributors were asked to "write up" descriptions regarding interactions with MAB doctors and email it to Professional Relations. By information and belief, the Professional Relations Department would transform these emails into allegedly supporting documentation for MAB doctor hours.

199. For instance, the 2005 Master Reference Documents lists Dr. Michael Hill as assigned to MIS projects in the Fixation R&D department. Dr. Hill was in Relator Hutcheson's region, and she did not observe Dr. Hill being engaged for any consulting service. Despite this, Relator Hutcheson's Monthly Scorecards reflect that Dr. Hill was paid \$2,500 for consulting or professional fees on 11 separate occasions, and was paid

\$5,000 on one occasion during 2004 and 2005. In an October 9, 2005 e-mail from Relator Hutcheson to Paul Sendro, it was noted that Dr. Hill was not engaged in any project at that time, but wanted to work on a white paper on the PEEK product. On December 13, 2005 Relator Hutcheson received an email from Professional Relations personnel Ilisa Rosselli asking for time entries for MAB doctors to be submitted "asap," also followed by a December 19 email that "we are a bit short on hours this month." Relator Hutcheson then requested that distributor Chris Burdett provide "input for Hill". On December 16, 2005, Mr. Burdett responded with the following email to serve as the time entry to cover 6 hours of consulting activity for Dr. Hill:

I met with Hill this month. On the 1st [meeting] we discussed the use of PEEK for TLIFs and PLIFs he was enquiring [sic] about modification of our instruments. They are too long and bulky and the spacers cannot be used with xray [sic] for contra-lateral distraction. Burdett and Hill sp[a]ced out the MSD instruments so I will probably try to make some customs for him. (3 hours) Yesterday we discussed a possible PLIF vs TLIF study. He is not sure if BMI would be interested or not. We messed around with the instruments that we are going to modify and talked about the ICON system. (3 hours)

200. Relator Hutcheson forwarded Mr. Burdett's email to Ms. Rosselli and asked whether the email from Burdett would be acceptable as a time entry. Ms. Rosselli emailed back that "I am going to doctor this up and put it in front of Bob [Robert Hastings]. But cutting the hours from 6 to 5, that is all he is required to have." Later that day, Ms. Rosselli emailed Relator Hutcheson with a revised entry for Hill, stating "This is what I did with the entry and put it in as a meeting with Bob. And just for 5 hours--his required amount." The entry had deleted references to customizing the instruments and that they had spent time on the instruments to be customized. Of note,

it was common business practice to make custom instruments for surgeon customers. The “doctored” entry also reflected that the conversation happened with Vice President Robert Hasting instead of with distributor Burdett.

E. BMI OFFERED MANY OTHER ILLEGAL INCENTIVES TO SURGEONS.

201. BMI offered and paid many other illegal incentives in order to secure additional surgeries utilizing BMI product, including grants, fellowships, royalties, and lavish entertainment.

202. BMI also regularly offered to pay surgeons for research projects or educational grants. These payments did not have commercially reasonable parameters and were above fair market value. Rather, the primary purpose of these arrangements was to secure their business.

203. The facts surrounding BMI’s relationship with Dr. Eidelson provide a clear example of BMI offering remuneration in exchange for a physician’s commitment to using BMI’s product. Relator Hutcheson had worked with Dr. Eidelson prior to being hired at BMI. When she moved to BMI, Dr. Eidelson informed her that he would be willing to use BMI’s products if BMI paid him \$1,500 a month, “supported” his website, and purchased his textbooks. Hutcheson related Dr. Eidelson’s payment requests to Vice President Paul Sendro and Division Manager Fred Munden at the January 2004 BMI national sales meeting. While Mr. Sendro considered a possible MAB position or a “marketing project” for Dr. Eidelson BMI instead decided to offer Dr. Eidelson an “unrestricted educational grant.” On April 7, 2004, BMI committed to Dr. Stewart Eidelson to pay an “unrestricted education grant” of \$18,000 to support “your research

of our product.” BMI also agreed to support Dr. Eidelson’s website, providing him with \$1,000 a month. BMI’s internal documents record that numerous payments were in fact made to Dr. Eidelson in 2004 and 2005 including the following:

- A May 2006 invoice reveals that BMI paid Dr. Eidelson \$500 for a “monthly advertising/sponsorship fee”.
- In December 2005, BMI sent Dr. Eidelson a check for \$4,500 in “sponsorship fees” to cover August of 2005 through April of 2006.
- Upon information and belief, BMI purchased 200 of Dr. Edilson’s book, *Advanced Technologies to Treat Neck and Back Pain, A Patient’s Guide* (March 2005).
- A February 28, 2005 email from Vivian Cruz (BMI Executive Assistant) to Relator Hutcheson stated that Dr. Eidelson had been sent a check for \$3, 000 to cover January and February of 2005, and also a check for \$1,500 to cover Mach of 2005.
- On April 20, 2005, Fred Munden send an email to Paul Sendro trying to ensure that Eidelson would receive continued payments for his “educational grant.” Munden states: “Paul, I sent you a message about continuing Dr. Eidelson’s [sic] agreement thru Susan’s budget thru 05, he has been paid for April but we need to make sure there are no glitches in May and for the rest of the year. Can you confirm that for us.” Sendro replied that: “I will need to run this through the Research committee (D. Johnson and R. Linnovitz) per the Fraud and Abuse policy you will hear about on the 3rd.” Upon information and belief BMI continued to regularly pay Dr. Eidelson.

See *supra* ¶ 120 for additional details regarding relationship with Dr. Eidelson.

204. By way of another example, in September 2006, Relator Hutcheson was shown documents provided by BMI to a licensed practical nurse, Geff Yielding, in which BMI offered Mr. Yielding substantial compensation, to include a commission, of \$1,000 per day in expenses, and two \$50,000 “unrestricted grants” if Mr. Yielding would ensure

BMI products were used by physicians with whom he had professional relationships.

Mr. Yielding stated that he declined BMI's offer.

205. BMI regularly offered and paid royalties to surgeons for the development of certain products. For example, BMI routinely paid Dr. Paul Keller royalties for the ICON product. Dr. Keller was the primary surgeon associated with the development of the ICON Product, which gained 510(k) approval in October of 2004 and was introduced to the market in spring of 2005. Relator Hutcheson's Monthly Report Card reflects that BMI regularly paid Dr. Keller a "professional consulting fees" in the amount of \$5,000 a month from late 2004 through 2005. As soon as ICON began to generate royalties, BMI paid Dr. Keller royalty fees instead of checks for consulting work.

206. The following additional doctors are examples of paid royalty arrangements, as a method of proving additional remuneration to doctors:

Surgeon	Royalty Products
Booth, Kevin	New Bridge laminoplasty system
Grant, Joseph	New Bridge laminoplasty system
Jordan, F. Richard	Hallmark Plate
Kabins, Mark	Unity Plate
Kozak, Jeffrey	Construx VBR PEEK System
Lewis, Adam Isaac	Unity Plate
Lorenz, Mark	Construx VBR PEEK System
Reed, Michael	Mesh
Zindrick, Michael	Construx VBR PEEK System

207. BMI also offered per diem "studies" to incentivize surgeons to use product. Upon information and belief, these studies were offered on a per-patient basis, such that a certain amount would be paid per surgical "case" studied. Relator Hutcheson was advised by another regional manager that the Western Divisional Manager at BMI would issue a letter, signed by former VP of Sales Paul Sendro, to surgeons with whom BMI did not have

business and would offer them in the range of \$2,500 per “case” for ten “cases” if they would “evaluate” a BMI system.

208. BMI often paid surgeons to participate in cadaver labs as a way to encourage surgeons to be more “involved with BMI” and consequently, use more of BMI products. For example, Relator Hutcheson was in charge of making arrangements for Dr. Kalman Blumberg to perform a cadaver lab demonstrating the use of various BMI products to approximately 28-30 sales representatives. Dr. Blumberg received high compensation for performing this lab at his facility. Dr. Blumberg was paid a \$15,000 fee to host the cadaver lab, as well as paying for breakfast, lunch, a fluoroscope and three cadavers, costing \$2,300-\$2,500 a piece. In addition to this, Dr. Blumberg was paid an above fair market value fee of \$2,500 fee for demonstrating use of the ICON product.

209. BMI was also willing to pay physicians with stock. Dr. Patrick Chan is a surgeon in Searcy, Arkansas, and a BMI MAB contractor from at least 2003 through 2006. BMI internal documents from November of 2005 show that Dr. Chan insisted on being paid in 2005 through a stock agreement before he would “move forward.” Upon information and belief, BMI agreed to give Dr. Chan stock options in lieu of checks.

210. Similar to Dr. Chan, Relator Hutcheson learned in 2007 from distributor Lance Cochran that Dr. Blumenthal did not like to be paid in cash, and preferred instead to be compensated with stock options.

211. BMI also offered lavish entertainment and other incentives in the courting of doctors to utilize BMI products.

212. Visits to BMI headquarters included exorbitant meals, entertainment, and lodging. For example, internal emails reflect that a BMI arranged a lavish VIP trip to New York for Dr. David Babat in hopes of successfully negotiating an MAB contract. Travel expenses were paid for Dr. Babat to fly to New York. Once there, Relator Hutcheson and distributor John Cook met Dr. Babat for dinner in Manhattan at Le Bernardino where they shared a 13-course meal at approximately \$300 per person. They were chauffeured by a limousine for the evening, and stayed at the W Hotel during the visit. After the VIP visit, Dr. Babat booked a number of surgical cases using BMI products, to prove his loyalty to BMI. Dr. Babat and details of his VIP trip are listed in November 10, 2005 meeting materials under “New Business Target.”

213. By way of another example, Dr. Patrick Chan participated in a “bone meeting” in early 2004 in Las Vegas with participants Boyle Cheng (BMI meeting organizer, Director of Biologics), Fred Munden (Manager of Eastern Division), Dr. Jordan, and Geoff Yielding. Dr. Chan expected to be “treated like royalty” and insisted on BMI paying for him to bring his wife and children with him and to travel first class. Relator Hutcheson was instructed to purchase 10 tickets to O (a Cirque de Soleil show) and book rooms for Dr. Chan and his family at the Bellagio Resort and Hotel.

214. Furthermore, Relator Hutcheson observed that Dr. Chan treated the sales representative for his distributor (Darby Adams) as a personal assistant – instructing her to pick up his wife from the hospital after a face lift, to babysit for him, and to run various errands for him.

215. Regional Manager Andy Janiak approved of numerous “perks” to Dr. Michael Mason including sailing trips, fishing trips, Patriot football games, and Jazz Fest.

216. Such incentives are common business practice for BMI: For example, a weekly report for the sales team documents on 9/25/2005: “Dr. [Howard] Reichman has several Hallmark cases booked for next week. He will be coming out to PGH and I will be taking care of his needs lots of fun and of course business. 10/2/2005 I will be flying to PGH on Friday to meet Dr. Reichman to golf at Oakmont and entertain D Johnson and Dr. Blumenthal Sunday.”

217. BMI managers and representatives were expected to do “whatever it takes” to make a surgeon happy and to secure that surgeon’s business. BMI managers and representatives provided exorbitant meals and entertainment for surgeons, including taking them to strip clubs and arranging for prostitutes.

218. Ms. Hutcheson was advised on or about September 29, 2006 by BMI distributor Lance Cochran that in one case, a female BMI sales manager was in Dallas, Texas and took surgeons to a strip club and, at the physicians’ urging, joined strippers on the stage, disrobed, and engaged with them in sex acts. BMI’s reaction upon learning of the incident was to demote the manager to a sales-representative position.

219. BMI encouraged its distributors to provide such entertainment and other paid incentives and, by information and belief, would sometimes compensate distributors for these paid incentives.

220. BMI distributor Chris Walsh regularly provided “gifts” such as a masseuse and wine, to Dr. Dan Cohen, a surgeon at the Orthopaedics and Spinal Associates of South Florida in Miami, Florida who was an MAB doctor during at least 2005. In December 2004, Relator Hutcheson attended a dinner held in Miami with Dr. Cohen, Matt Lyons, Fred Munden, Mr. Walsh and his employer, Chris Burdett, to discuss a potential MAB contract with Dr. Cohen. Mr. Munden gave Cohen a framed Red Sox memorabilia at this dinner.

221. BMI distributor Chris Burdett (owner of Marlin Medical) regularly provided “extras” to Dr. Michael Hill, a surgeon at the Florida Neurology Institute, Inc. in Leesburg, Florida. Dr. Hill was a BMI MAB contractor from at least 2003-2005, and ranked 14th for volume of sales to all doctors. Mr. Burdett was very willing to provide Dr. Hill with “extras” in addition to the consulting fee, to keep Dr. Hill’s business.

222. For instance, Mr. Burdett took Dr. Hill to the Indianapolis 500. Mr. Burdett also stated to Relator Hutcheson that he would even be willing to pay for Dr. Hill to take a trip to Brazil to visit his girlfriend whom he was unable to get into the country. Mr. Burdett also offered to bring Dr. Hill’s girlfriend in from the Bahamas, either in his plane or his boat, and offered to allow her to use his sister in law’s passport.

223. Mr. Burdett also provided cash incentives to Dr. Hill’s office staff. Upon information and belief, Mr. Burdett gave Dr. Hill’s staff American Express gift cards for their personal use. In at least 2005, Mr. Burdett gave Dr. Hill’s office \$200.00 a week, which he characterized as a “guarantee”, and also provided them reimbursements for lunches.

224. Additionally, Mr. Burdett arranged a steep discount on BMI products to Leesburg Regional Hospital, where Dr. Hill performed surgeries. In a letter from Burdett to Dr. Hill dated June, 22, 2004, Burdett points out that he was able to arrange a 27% discount off of Blackstone's list price, where the standard discount is 10%.

225. Burdett made cash payments to Dr. Hill over and above his monthly MAB stipend and other paid incentives. Upon information and belief, Burdett carried thousands of dollars in cash with him, which he used to bribe doctors to use BMI products.

F. BMI'S RESULTS: SURGERIES USING BMI PRODUCTS.

226. BMI's schemes resulted in the scheduling of increasing numbers of surgeries using BMI products.

227. The purchase of BMI products for use in these surgeries involved close interaction with both the surgeon and the hospitals.

228. The surgeon makes the decision regarding whether a surgery is performed and the product that will be used in the surgeries.

229. Once a surgery is scheduled, the surgeon or surgeon's office contacts the Blackstone sales representative so that the sales representative can get the product to the hospital.

230. The sales representative is responsible for obtaining the product needed in advance of the surgery, either through use of his or her own "consignment set" or by calling Blackstone. Sales representatives often have "consignment sets" of various high-volume products on hand for this purpose. The sales representative is also

responsible for getting the product set to the hospital in time for it to be appropriately sterilized prior to surgery.

231. The BMI sale representative is present for each surgery. At the end of the surgery, the sales representative must complete a Sales Order Request Form, which itemizes what was used during the surgery. The Sales Order Request Form also records the date of surgery, the surgeon's name, the patient's name or patient I.D. number (depending on iteration of the form used), the number of levels performed (if applicable), and the name of the hospital being billed for the product.

232. For example, Sales Order Request Form E2804, documents that Dr. St. Louis performed a surgery using 18 screws, 2 rods, and one bone drill on patient L.,⁵ age 59, a patient of Dr. James Nelson, on May 10, 2004, at Roy Lester Schneider Hospital in St. Thomas, Virgin Islands. Per the notes on the form, the form was delivered to Materials Management at the hospital.

233. Blackstone's Distributor Reference Guide contains a section entitled "How to Complete a Sales Order Form," which states that surgeon's name is collected for "tracking, billing, and sales reporting purposes."

234. The sales representative then sends the completed Sales Order Form to Blackstone, generally by facsimile.

235. The sales representative also takes the completed Sales Order Request Forms to a hospital representative after a surgery is complete in order for a Purchase Order ("P.O.") number to be assigned. This may be given to the Neurological/

⁵ The patient's name was redacted to preserve patient confidentiality and can be provided

Orthopedic Coordinator at the hospital, or to the Materials Management or Purchasing Department.

236. The Neurological/Orthopedic Coordinator at the hospital is integral to every surgery in which Blackstone product is used. The coordinator has a management role, and oversees the circulating nurse, scrub nurse, and other staff at each surgery, and generally receives the Blackstone Sales Order Request Form after surgeries where Blackstone product was used.

237. After receipt of the Sales Order Request Form, the hospitals then assign a purchase order number to the sales order request, and will communicate that number to the sales representative.

238. The sales representative then conveys the P.O. number to Blackstone, generally by phone or facsimile.

239. When the P.O. number is issued, the sales representative gets credit for surgery for commission purposes.

240. Once the P.O. number is received, BMI issues an invoice to the hospital. BMI's Invoices reflect the hospital name, and contact information, the distributor, the items ordered for the surgery, and the pricing. The invoice also reflects the surgeon's name, patient's name, initials, or identifiers, the date of the surgery, and the levels performed (if applicable).

241. The following are specific examples of information on BMI Invoices, reflecting surgeries using BMI products:

upon request.

On Invoice No. 37098, BMI invoiced Emerald Coast Hospital, Sacred Heart, in Destin, Florida, for a surgery using 3 Degree, in the amount of \$2,434.00. The surgeon's name was Dr. Dale Johns, the patient's name was T. (last name initial), and the surgery date was 5/12/04.

On Invoice No. 37169, BMI also invoiced Emerald Coast Hospital for another surgery using 3 Degree, in the amount of \$2,439.00. The surgeon's name was Dr. Gus Arriola, the patient's initials were D.A., and the surgery date was 5/20/04.

242. Thus, BMI has records tracking the provider names, date, and patient identifiers for every surgery performed using its products.

**G. BMI KNEW THAT THE SURGERIES RESULTED IN CLAIMS TO
FEDERALLY-FUNDED HEALTHCARE PROGRAMS**

243. As previously articulated in Section IV.B., the surgeries performed with BMI products result in the submission of false claims to Medicare, Medicaid, and other federally funded healthcare programs. These false claims include both the claims submitted by the hospitals for the surgeries and the claims submitted by the physicians.

244. Representative examples of these false claims submitted as a result of BMI kickbacks to physicians are contained in the attached as Appendix 2 (A-D). These particular false claims were submitted under Medicare Part B by three BMI MAB contractors practicing in the District of Massachusetts, who were paid by BMI with the purpose of inducing use of its product in spinal surgeries they performed.

245. BMI's business model was predicated on offering surgeons incentives to schedule more surgeries using BMI products (*see, e.g., supra*, Section V.B. on Monday Report entries regarding purpose of physician incentives).

246. Indeed, BMI offered and paid inducements to surgeons with the purpose and expectation that the surgeon would commit to using BMI product in all his or her

surgeries, in essence to give BMI all of its business.

247. In fact, if a surgeon began using a competitor's products while being paid by BMI, its practice was to "terminate" that surgeon (See, e.g. ¶ 126, regarding Massachusetts MAB Dr. Mason, who "has been giving all his cases to MSM as promised").

248. BMI knew that the surgeries scheduled by the physicians it incentivized would result in claims to federally-funded healthcare programs, by both the physicians and the hospitals.

249. As previously articulated, BMI issued a power point for its employees when it revised its documentation requirements for its paid physicians because it was worried about "Justice Department, Audit, Exposure." November 14, 2005 Medical Advisory Board Consulting Training. BMI well knew that its illegal incentives resulted in exposure for federal prosecution.

250. Indeed, the March 2007 Annual Report filed by Orthofix, on behalf of Blackstone and its other affiliates, spells out that it is aware that its business practices result in claims to Medicare, Medicaid, and Tricare:

Reimbursement policies of third parties, cost containment measures and healthcare reform could adversely affect the demand for our products and limit our ability to sell our products.

Our products are sold either directly by us or independent sales representatives to customers or to our independent distributors and purchased by hospitals, doctors and other healthcare providers. These products may be reimbursed by third-party payors, such as government programs, including Medicare, Medicaid and Tricare, or private insurance plans and healthcare networks. Third-party payors may deny reimbursement if they determine that a device provided to a patient or used in a procedure does not meet applicable payment criteria or if the policy holder's healthcare insurance benefits are limited.

251. Further, its public filings also make clear that it is aware that:

Our sales and marketing practices are also subject to a number of U.S. laws regulating healthcare fraud and abuse such as the federal Anti-Kickback Statute and the federal Physician Self-Referral Law (known as the “Stark Law”), the Civil False Claims Act and the Health Insurance Portability and Accountability Act of 1996 as well as numerous state laws regulating healthcare and insurance.

March 16, 2007 Form 10-K, “Government Regulation.”

252. More to the point, BMI knew that any change in Medicare, Medicaid, or other federal payor’s reimbursement methodologies would significantly affect its business. For example, Paragraph 8.8 of at least one version of BMI’s consulting agreement specified:

Change of Circumstances. In the event (1) Medicare, Medicaid, any third party payor or any federal, state or local legislative or regulatory authority adopts any law, rule, regulation, policy, procedure or interpretation thereof which establishes a material change in the method or amount of payment for services under this Agreement, or if (ii) any or all such payors/authorities impose requirements which require a material change in the matter of either party’s operations under this Agreement, then, upon the request of either party materially affected by any such change in circumstances, the parties shall enter into good faith negotiations for the purpose of establishing such amendments or modifications as may be appropriate in order to accommodate the new requirements and change of circumstances while preserving the original intent of this Agreement to the greatest extent possible. If, after thirty (30) days of such negotiations, the parties are unable to reach an agreement as to how or whether this Agreement shall continue, then either party may terminate this Agreement upon thirty (30) days’ prior written notice.

253. By way of another example, Relator Hutcheson knew that BMI fielded questions from providers about the Medicare reimbursement applicable to its products. For example, in an email dated October 4, 2005, from distributor John Dunham to BMI representatives and management, including two of the Lyons brothers, he advises:

From: John Dunham
Sent: Tuesday, October 04, 2005 12:48 PM

To: Bill Lyons; Matt Lyons; Paul Sendro
Cc: Kevin Boulay; Kiki Steinberg; Thierry Chaney; Brian Dukate; Andrew Janiak;
Fred Munden; Rita Patel
Subject: Construx Mini Surgeon Reimbursement

Gentlemen,

I hope all is well. Per our discussions during NASS and the utilization of the Construx Mini. I wanted to update you regarding surgeon reimbursement for cages vs. machined allograft. This also holds true for our entire PEEK line (ALIF, PLIF, TLIF).

22851 code for Cage; average reimbursement \$500

20931 code for Structural allograft; average reimbursement \$100

* The 22851 is also a stand alone code meaning that the surgeon is reimbursed the full amount every time and it's not part of the total procedure (multiple coding) cycle.

* The 20931 code is usually the 3rd or 4th code (with multiple codes) used often times resulting in a reduced payment

254. Consistent with this practice of providing coding information, Orthofix also asserts on its corporate website that it routinely provides both diagnostic (Part A) and procedural (Part B) coding:

Orthofix routinely provides customers with information about appropriate coding of their devices. We understand that information provided by Orthofix in this manner can significantly simplify a provider's or supplier's task in determining how to bill for these products. Orthofix solicits confirmation of correct coding directly from CMS.

Accordingly, CMS and other payers, in reviewing for appropriate billing, will regard such information as, in general, reasonable support for a coding decision with respect to whether a payment was appropriate.

Listings of codes, whether diagnostic or procedural, represent those that may apply to that patient encounter. It is the customer's responsibility to determine which combination of codes from this listing actually applies to that specific patient encounter. Providers of services or items are ultimately responsible for the content of the bills they present to Medicare or any other payer.

Orthofix website, under "Coding," <http://www.orthofix.com/coding/disclaimer.asp>.

255. Moreover, BMI's model is also highly-focused on the hospital side of the relationship. Its goal is to transform the surgery opportunity into a BMI sale, and its internal communications are replete with illustrations of this goal.

256. For example, one of its tracking records was called a S.M.A.R.T. (“Specific, Measurable, Attainable, Realistic, Trackable”) Goal Worksheet, with the stated purpose of providing “details of your plan to convert the business to Blackstone.” The worksheet reflects entries by various sales representatives to record the target “surgeon, city, hospital,” the estimated sales volume in dollars, the “# of surgeries per week,” the “action steps to convert business,” the measurement indicators of success,” and the “obstacles.”

257. Example entries on this worksheet reflect that “action steps to convert business” of target surgeons at various hospitals include:

Build relationship. Work with hospital relationship. (Dr. Cowan, Rock Hill, SC).

Leverage hospital’s role as an education facility and need to expose residents to multiple sets. (Dr. Birkedal, Winston Salem, NC, NC Baptist Hospital).

Trying to utilize his colleagues who are already using BSM. (Dr. Chewning, Statesville, NC, Davis Regional MC, Iredell Memorial Hospital).

Utilizing Hospital contacts to gain insight into preferences. (Dr. Gooch, Statesville, NC, Davis Regional MC, Iredell Memorial Hospital).

Utilizing relationship with hospital to try to get a few trials (Dr. Williamson, Statesville, NC, Davis Regional MC).

Leveraging relationships at the hospital to try and find the best way to convert. (Dr. Rosenfeld, Hickory, NC, Frye MC).

S.M.A.R.T. Goals worksheet (cover letter indicates entries from sales team were due February 2005).

258. BMI’s Monday Report entries also reflect interaction with the hospitals in order to convert business, including to sponsor fellowships, provide grants, or rebates to “increase BMI use”, which are included in the following chart:

Surgeon	Region	Location	Hospital	MONDAY REPORT EXCERPTS
Dr. Jed Clawson	MT			<u>10/30/2005: New Business</u> "Dr Clawson, NEW user is going to evaluate BSM soon. We are also going to evaluate Trinity at The Univ of Utah."
Dr. Lyal Liebrock (deceased)	MT	Omaha, NE	University of Nebraska Medical Center	<u>6/12/2005: New Business</u> "University of NE, Dr Liebrock 3 level case that went great 2 weeks ago. We are trying to get them on board via a grant for their Dept."
Dr. Pradeep Narotam	MT	Terre Haute, IN	Union Hospital	<u>9/25/2005: Lost Business</u> "Dr Narotam; however I have began to look for a new Dist in the area and have set up a dinner with him on the 22 of Sept. I am keeping Spicer out of the picture. They are on their way out." <u>9/25/2005: New Business</u> "Helio and I have a dinner with Dr Narotam this week." <u>10/2/2005: New Business</u> "We had a good dinner with Dr Narotam look for him to start to use Hallmark and POSCTS soon" <u>10/16/2005: New Business</u> "We had a good dinner with Dr Narotam; look for him to start to use Hallmark and POCTS soon" <u>12/4/2005: Status Update</u> "I will be in NE to have dinner with Dr Narotam to discuss support of his fellow at Creighton University."

Surgeon	Region	Location	Hospital	MONDAY REPORT EXCERPTS
Dr. Pedlow	NE	Boston, Massachusetts	Massachusetts General	<p><u>9/25/2005</u> “Dr. Pedlow from Mass General will begin using SFS for scoliosis at NEMC where Dr. Weller practices.”</p> <p><u>10/2/2005</u> “NASS meetings/dinners set up for Drs. Mason, Shore, Rumi, Pedlow, Mansfield, Woods”</p> <p><u>10/16/2005</u> “Dr. Pedlow now using Icon”</p> <p><u>10/23/2005</u> “Productive meetings with surgeons at CNS: Mason, Ozuna, Pedlow, Shore, Ghogawala, Ho, Koh, Degen.”</p> <p><u>11/6/2005</u> “We need Matt L to follow-up ASAP with Drs. Mason and Shore. Also schedule Matt to meet with Dr. Pedlow at Mass General. Trinity pricing/reimbursement questions are arising as we have begun using in cases-Billy and Tom Brewer are in the loop to sort this”</p>
	SE	Leesburg, FL	Leesburg Hospital	<p><u>8/7/2005: Status Update</u> “Prepared a rebate contract w Mike L for Leesburg hospital that should increase BMI use.”</p>
	NE	Camden, NJ	Cooper Univ MC? UMDNJ	<p><u>8/14/2005: Lost Business</u> “All of the new business at Cooper Univ MC/UMDNJ is at risk as a result of grant situation”</p> <p><u>11/6/05: Status Update</u> “Dr Davis' pull has gotten us approved as a vendor at Johns Hopkins main campus. There are several of our current users who can now utilize BMI at Hopkins.”</p>

Surgeon	Region	Location	Hospital	MONDAY REPORT EXCERPTS

259. The use of fellowship programs to convert business is just another illustration of the wide array of incentives offered by BMI to induce providers to increase the number of surgeries using BMI products. In an October 2005 email, the sale team records the directives from Matt Lyons to increase business:

From: Andrew Janiak
 Sent: Wednesday, October 05, 2005 8:09 AM
 To: Fred Munden; Paul Sendro
 Subject: Northeast Region Action Items

Fred and Paul, as follow up from the meeting with Matt Lyons at NASS. here are the action items required for the Northeast Region to meet the goals spelled out by Matt ...

* * *

3) Sponsor Fellowship Program at Beth Israel Deaconess Hospital in Boston. The program is run by Dr. Paul Glaser, the current Fellow is Dr. Frank Hayward.

260. BMI purchased data to track the volume of spinal surgeries at hospitals across the country in order to attempt to track its "penetration" at each hospital in terms of sales volume.

261. In an email dated November 17, 2005, Vice President of Marketing Matthew Fruschell discusses the purchase of hospital market share data to the sales team:

Ladies and Gentlemen;

A few words on the market share data. This data comes from actual in-patient hospital discharge data, the latest actuals are from 2003. All the big spine

companies purchase this data and then scrub it. We compute an average weighted fusion procedure cost to get to 2005 imputed sales by hospital. A lot happened in spine over the last 18-24 months therefore some anomalies can present themselves. Hospitals close, hospitals open, big cutters come and go and the young spine turks are showing up everywhere; post fellowships. When you identify an anomaly and it is important to your tactical plan discussions with your distributors please let me know and I will address it with the data house.

On an update note, we will be scrubbing the GPO market data, by hospital, next week. This will provide us the landscape of opportunities for regional and national contracts. This is an initiative that Paul and I will be tackling in the upcoming months. Second, we just purchased some data that will cut up the fusion market into procedure chunks. The raw data will arrive next Tuesday. Finally, let me know what you would like to see by way of data information.

262. From its first contacts with target physicians, BMI tracked the use of BMI product at the surgeon's affiliated hospital(s). One of the first questions of the "Surgeon Visit Questionnaire" is his or her affiliated hospital(s).

263. BMI's internal sales tracking records the hospitals affiliated with surgeons and with distributors. For example, one such tracking form is entitled "Top 15 distributors with their top 10 hospitals."

264. BMI also negotiates favorable pricing agreements, through the use of discounts and rebates, to incentivize increased volume from the hospitals.

265. In addition, the hospitals are well aware what medical device companies are being selected by each surgeon, as it issues the purchase order for the product for each surgery. Because the surgeons dictate whether the surgeries are performed and what products are used, hospitals may be dealing with multiple medical device suppliers when issuing purchase orders for surgeries depending on the surgeon's relationships with particular suppliers.

266. The hospitals routinely negotiate the price, particularly because the market is competitive and many companies offer discounts in exchange for higher volumes of business.

267. BMI negotiated discount arrangements with many providers as a means to induce more business.

268. BMI had discount or rebate programs available for hospitals based on the hospital's "compliance level," which, in BMI parlance, meant the level of percentage of BMI product sold to the hospital vis-à-vis total spinal surgeries performed at the facility.

269. For example, a May 1, 2005 pricing sheet for the 3 Degree Anterior Cervical Plating System reflected decreasing pricing depending on increasing "Compliance Levels"

- 75% Compliance, Level 0
- 80% Compliance, Level 1
- 85% Compliance, Level 2
- 90% Compliance, Level 3
- 95% Compliance, Level 4
- 100% Compliance, Level 5

270. BMI also negotiated discount pricing arrangements with group purchasing organizations, often composed of physicians. One example is a purchasing agreement with M Cubed Medical dated October 15, 2005. BMI agreed to provide its products according to a discounted pricing schedule and through a group of certain distributors to the members of M Cubed Medical. BMI promised to offer M Cubed Medical the best available prices in its market. BMI also promised to pay M Cubed a commission based on net sales under the agreement.

271. An excerpt from the Monday Report from July 3, 2005 also reveals that

BMI was considering a group discount for a group of surgeons led by Dr. Alan Brown, a surgeon practicing in Salt Lake City, Utah, in order to encourage their use of BMI products. The note states:

Dr Brown is putting a group together of 10 -15 spine surgeons and are looking for the best price on all products. They look to be at 1 million per month w/in the next year. I met w/ Dr Moer who is part of the group, and is a 1.25 million metal guy. They did 100,000 in screws alone last month. I propose we do a hybrid offer with what price they want and give the dist around 10%. This group will provide their own coverage and the prices they want are legit. I am good friend w/ Dr Brown I will update everyone with an email later in the week as we need to do this to gain new business and take business away from Lynx and K2 call for details.

H. BMI'S CONDUCT IS KNOWING AND ONGOING.

272. BMI knowingly and willfully and pervasively paid kickbacks to orthopedic surgeons to induce them to use its products. BMI knew that the payment of these kickbacks resulted in the use of its products in spinal surgeries performed on Medicare, Medicaid and other federally-funded patients.

273. In addition to BMI's actual knowledge of this fact, it was foreseeable that the surgeries scheduled using its products would result in claims to federal payors by both the hospitals and the surgeons. Each of these claims is in violation of the Anti-Kickback Act, and the thereby is in violation of a condition of payment for those claims.

274. BMI knowingly caused the submission of false claims to the United States for spinal surgeries performed on Medicare, Medicaid and other federally-funded patients.

275. Defendant acted knowingly, as that term is defined in 31 U.S.C. § 3729(b).

276. The scheme to cause the filing of false claims described herein was pervasive and nationwide and took place for many years and, upon information and belief, is ongoing. Upon information and belief, this conduct has been ongoing since Blackstone began operations in 1996.

277. Based on Relators' positions in the industry, they are personally aware that BMI's paid relationships continue into the present. Relator Hutcheson has had ongoing communications with sales representatives and other individuals in the industry and has been advised that, as late as 2008, BMI was trying to re-establish relationships with large distributors based on promises of signing bonuses, larger commissions, and the ability to offer paid relationships to secure business.

278. BMI's kickback scheme was far-reaching and complex, involving thousands of paid arrangements and incentives in various forms to hundreds of surgeons over a long period of time. The full details of these schemes are in the exclusive possession of the Defendants.

**COUNT I: VIOLATIONS OF THE
UNITED STATES CIVIL FALSE CLAIMS ACT**

279. The allegations of foregoing paragraphs are realleged as if fully set forth herein.

280. The False Claims Act, 31 U.S.C. § 3729(a)(1)(A) and (B), imposes liability upon, *inter alia*, those who knowingly cause to be presented false claims for payment or approval, and those who make or use, or cause to be made or used, false records or statements material to a false claim.

281. Defendant deliberately engaged in a concerted, vigorous, and cynical campaign to induce physicians to perform surgeries utilizing its medical products by paying illegal kickbacks.

282. Claims for payment to federally-financed healthcare systems, to include at least Medicaid, Medicare, and Tricare, which resulted from Defendant's knowingly-illegal kickback campaign were false claims.

283. The false claims referenced in the foregoing paragraph were caused to be presented by Defendant, in violation of 31 U.S.C. §3729(a)(1)(A).

284. Defendant's kickbacks to physicians and others were intended to, and did, cause the submission of false claims by hospitals and physicians, in violation of 31 U.S.C. § 3729(a)(1).

285. By entering into sham agreements with providers, including consulting agreements, educational grants, per diem studies, fellowships, and other agreements, Defendant made and used false records or statements material to false claims.

286. Because compliance with the Anti-Kickback laws are a condition of payment of federal healthcare programs, Defendant's anti-kickback violations, and the false records and statements created as a result, have a natural tendency to influence the payment of claims resulting from Defendant's conduct.

287. By offering and paying illegal inducements, Defendant caused providers to violate conditions of payment for the claims submitted by those providers. Defendants also caused providers to falsely certify compliance with anti-kickback laws, and such certification is material to the payment of false claims submitted by those providers.

288. Because the United States would not have paid for services which it knew to have been the result of illegal kickbacks, the United States has been harmed in an amount equal to the value paid by the United States.

289. The United States Government has been damaged as a result of Defendant's conduct in violation of the False Claims Act in an amount to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, Relators requests:

1. That the Court enter judgment against Defendant in an amount equal to three times the amount of damages the United States Government has sustained because of Defendant's actions, plus a civil penalty of \$11,000 for each action in violation of 31 U.S.C. § 3729, and the costs of this action, with interest, including the costs to the United States Government for its expenses related to this action;
2. That in the event that the United States Government intervenes in this action, Relators be awarded 25% of the proceeds of the action or the settlement of any such claim;
3. That in the event that the United States Government does not proceed with this action, Relators be awarded 30% of the proceeds of this action or the settlement of any such claim;
4. That Relators be awarded all costs, attorneys' fees, and litigation expenses;

5. That the United States Government and Relator receive all relief, both at law and in equity, to which they may reasonably appear entitled.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing was sent via the Court's electronic filing system, and served to all counsel of record on June 4, 2009.

/s/ Jennifer M. Verkamp
Jennifer M. Verkamp